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ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN AND
RELATED MATTERS.

Hearing held
8th floor
180 Dundas Street West
Toronto, Ontario

The Honourable Mr. Justice S.G.M. Grange

Commissioner

P.S.A. Lamek, Q.C.

Counsel

E.A. Cronk

Associate Counsel

Thomas Millar

Administrator

X Oxford
Transcript of evidence
for

December 2, 1983

Simon
Stonehouse Jr.

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1 ROYAL COMMISSION OF INQUIRY INTO CERTAIN
2 DEATHS AT THE HOSPITAL FOR SICK CHILDREN
3 AND RELATED MATTERS.

4 Hearing held on the 8th Floor,
5 180 Dundas Street West, Toronto,
6 Ontario, on Friday, the 2nd
7 day of December, 1983.

8 THE HONOURABLE MR. JUSTICE S.G.M. GRANGE - Commissioner
9 THOMAS MILLAR - Administrator
10 MURRAY R. ELLIOT - Registrar

11

12

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23		
24		

25

(Cont'd)



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VOLUME 74



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1
2 ---Upon commencing at 10:00 a.m.
3
4

5 DR. RALPH KAUFFMAN, Resumed
6
7

8 MS. THOMPSON: Good morning, Mr.
9 Commissioner.
10

11 THE COMMISSIONER: Yes, Miss
12 Thompson.
13

14 MS. THOMPSON: Just to follow up
15 on something that was raised yesterday. Mr. Hunt
16 asked for a reference to Dr. Bain's testimony
17 respecting the 16 children he cited to have
18 convulsions or seizures. That information is found
19 in the examination by Mr. Labow, Volume 62, page
20 3894. Dr. Bain names the 17 children there
21 including a Baby Hotchinkson and that baby is not
22 one of our 36, the others are.
23

24 THE COMMISSIONER: Yes. So, there
25 are actually 15 then, is that it?
26

27 MS. THOMPSON: No, there were 17
28 babies.
29

30 THE COMMISSIONER: 17, I see.
31

32 MS. THOMPSON: And Hotchinson was
33 not one of our babies. So, that would leave 16
34 of our 36 babies.
35

36 MR. ORTVED: What was the volume
37 number again?
38

39 MS. THOMPSON: Volume 62 at page
40
41

A
BB/cr



1

2 3894.

3 MR. HUNT: I also found another
4 reference to Dr. Bain's evidence re seizures.

5 THE COMMISSIONER: Yes, all right.

6 MR. HUNT: It is Volume 63, pages
7 4099 to 4103. It is in Mr. Lamek's re-direct
examination.

8 THE COMMISSIONER: Yes, all right,
9 thank you.

10 MS. THOMPSON: Thank you, Mr. Hunt,
11 I am grateful to you.

12 MR. HUNT: You are welcome.

13 THE COMMISSIONER: Mr. Ortved.

14 MR. ORTVED: Thank you, Mr.
15 Commissioner.

16 CROSS-EXAMINATION BY MR. ORTVED:

17 Q. Dr. Kauffman, my name is
18 Ortved and I appear here for a number of the doctors
19 at the Hospital for Sick Children and including
among them are the clinicians in the Cardiology
20 Ward.

21 As I understand your evidence, you
22 performed an analysis of the deaths, principally
from a pharmacologic point of view?

23 A. Yes, that was the request to

24

25



1

2 me and I then secondarily considered all the other
3 information available to me.

4 Q. Right. You took into account
5 all of the available data which you have outlined for
6 us and that included the clinical data, correct?

7 A. That is correct.

8 Q. And as I understand it, you
9 are a paediatrician?

10 A. That is correct.

11 Q. Not just a paediatrician but
12 as I understand it have responsibilities as a
13 clinical co-ordinator and as an attending physician
14 on a ward at the Children's Hospital in Detroit, is
15 that correct?

16 A. That is correct.

17 Q. And included among those
18 patients for whom you have responsibility from time
19 to time would be cardiac patients?

20 A. That is correct.

21 Q. So, I take it then that
22 assessing the clinical picture is something that
23 you felt competent to do?

24 A. I felt competent to the
25 extent that any experienced paediatrician would be
competent. I would not compare my competence to a



1

2 seasoned cardiologist.

8

A. No, not only the post mortem values

10

0 No. 2

11

A. I had to take into consideration all digoxin measurements that I had available to me.

2

Q. Right, and I am not suggesting that you didn't, I am just saying that the digoxin data in total, including the post mortem values, were of critical importance to your analysis?

16

A That is correct.

17

Q. And that obviously is the case, having regard to what you have told us, is the difficulty in distinguishing between death due to digoxin poisoning and death by natural causes in a child suffering severe cardiac disease, correct?

21

A. It is a difficult distinction to make.

23

Q. And that is why the digoxin

24

25



1

2 data was of such importance in your analysis?

3 A. It was of importance because
4 it was one possibility and it was I think the
5 primary reason I was asked to even look at the babies.

6 Q. Sure. And whereas the
7 terminal symptoms may have been equivocal, if I
8 can put it that way, the digoxin data might, as you
9 put it, provide you with the objective evidence to
come down on one side or the other?

10 A. I don't know if I could go
11 that far because I think that the digoxin evidence was
12 important to me and, as we all know, it was of
13 varying quantities and quality in the different
14 cases. So, sometimes it was quite helpful and other
times it was not very helpful.

15 Q. Right. And in those cases,
16 and I don't think we are far apart here, in those
17 cases where it was helpful, Dr. Kauffman, it assisted
18 you in deciding whether a particular death which,
19 by its symptoms, may have been equivocal, was in fact
reasonably probably due to digoxin poisoning?

20 A. I think that is correct, yes.

21 Q. Now, what I would like to do
22 is just deal with the deaths that you analysed
23 sequentially - not all of them you will be happy to

24

25



1

2

hear, Mr. Commissioner - and concentrating specifically
on those deaths which you felt able to express an
opinion were reasonably probably likely due to
digoxin poisoning. The first of those deaths, as I
understand it in terms of time, is the death of
Stephanie Lombardo, correct?

7

A. I haven't listed them in
chronological order, so, I can't answer you with any
certainty. I will take your word for it if you tell
me that.

11

Q. All right. Well, I am dealing
with those deaths which, on your ratings, you rated
3 or above, all right?

13

A. That is correct.

14

Q. Those are deaths you have told
us you felt confident saying were reasonably probably
likely due to digoxin poisoning?

17

A. Yes.

18

Q. Just take it from me for the
moment, Dr. Kauffman, someone here of the greater
A will correct me if I am wrong that the earliest of
those deaths in terms of time is Stephanie Lombardo,
all right?

22

23

24

25

A. I think she died on 23
December, '80.



1

2 Q. That is correct.

3 A. Yes.

4 Q. And it is clear, I put it to
you, having regard to your report filed here as
5 Exhibit 266, that the critical feature in your opinion
6 regarding your conclusion insofar as Stephanie
7 Lombardo was concerned was the positive finding for
8 digoxin in a child for whom no digoxin was prescribed.

9 A. I think that was a very
10 important piece of information to me at the time.

11 Q. Right. And an additional
12 feature or an additional factor is your opinion that
13 her clinical course was, as you told Mr. Strathy
14 yesterday, not incompatible with digoxin intoxication?

15 A. That is correct.

16 Q. And to expand upon that, I
17 don't think I would be taking any liberties to suggest
18 that you were impressed with what you perceived as
19 her sudden deterioration?

20 A. Yes.

21 Q. Particularly having regard
22 to the fact that, as you saw it, she had been stable
23 for a period of days?

24 A. Yes.

25 Q. Now, you, I take it, are you



1

2 aware, because you told Miss Cronk, that the clinicians,
3 Dr. Rowe in particular telling us ascribed a different
4 cause of death to Stephanie Lombardo, namely, occlusion
5 of her shunt, correct?

6

A. I don't remember at the moment
6 that he said that.

7

Q. All right.

8

A. I am not disagreeing with
9 you I just don't remember it right now.

10

Q. All right.

11

A. I recall that it was
11 suggested to me that he at the time thought that that
12 was a likely possibility.

13

Q. Right. And you I think
14 indicated in your evidence that you acknowledge
15 that that would be a reasonable conclusion?

16

A. That is correct.

17

Q. And in fact I think you went
17 on to say in your evidence, the next day on November
18 29th, and I am referring to Volume 71 at page 5579.

19

THE COMMISSIONER: Do you have a set
20 of transcripts?

21

THE WITNESS: No. I wish if I could
22 see a copy of my testimony as we refer to it.

23

MS. CRONK: Here is one, Doctor.

24

25



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2

MR. ORTVED: Thank you very much, Miss
Cronk.

4

5

THE COMMISSIONER: We haven't another
set, I take it, available?

6

7

MS. CRONK: No, we don't, sir.

THE COMMISSIONER: Well, that is going
to be awkward for you.

8

9

MS. CRONK: I will see what I can do,
sir.

10

MR. HUNT: We have an extra one here.

11

12

13

THE COMMISSIONER: Have you an extra
one. I wonder, if you have an extra one if you could
put all three - well, how many have we got now, we've
got three?

14

15

16

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18

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DM.jc

B 1

2 Q. Do you have that record, Doctor,

3 Volume 71?

4 A. Volume 71?

5 Q. Volume 71, page 5579.

6 A. Right, I have it.

7 Q. And the question, Dr. Kauffman,
is:

8 "Q. Doctor, let me be clear about
9 this. If the shunt had in fact
10 occluded, and I recognize that we
11 don't have any autopsy or pathological
12 findings to assist us in a confirming
13 sense in that regard, but I ask you
14 to assume that it had, all right. If
15 that had occurred, Doctor, of the
16 terminal events that this child
17 suffered, the mode of her dying and
18 the cause of those events, including
19 the nature of her cardiac arrest,
20 consistent in your view, could they
21 be caused merely by the occlusion of
22 the shunt?

23 "A. Yes, I think so, I think they
24 could be. I think that in the absence
25 of digoxin levels being detected in



B.2

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"the tissue that would be the most
plausible scenario to explain her
death even in the absence of an
autopsy."

5

6

And then you go on to talk about the digoxin in the
exhumed tissue, and I don't intend to refer to that
now unless someone asks me to. I think the wording
you applied to it is most plausible, sir, correct?

9

A. That is correct.

(2)

10

Q. And that is something that you
hold to today?

11

A. Yes. In the absence of digoxin
data I think that was a reasonable assumption at that
time.

12

Q. And just on the subject of
your opinion as to the child being stable in the
period prior to her death, do you have a copy of the
Lombardo chart; I think Mr. Elliot can provide it to
you.

13

A. I can get one.

14

Q. This is Exhibit No. 78.

15

A. Okay.

16

Q. First, before we look at the
chart in detail, I would just ask you to agree with
me that, Doctor, whenever you have a child who is

17

18



B.3

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2 suffering from severe cyanotic heart disease, who
3 has undergone an operation within the first three or
4 four days of her life, in any event you have a child
5 who is at some degree of risk, correct?
6

A. That's correct.

7 Q. And certainly if I could ask
8 you to turn to page 37 of that Hospital record. You
9 will see, Doctor, there a reference at the bottom of
10 the page under date 18/12/80, and it is somewhat
11 illegible, it has been --

A. Right at the bottom?

12 Q. Yes.

A. Yes.

13 Q. And I understand that reference,
14 and the evidence will bear me out I believe, that that
15 was made by a Dr. Burns who is a qualified cardiologist
16 who was training in Intensive Care. It reads, the
17 typed line of that reference reads:

18 "Only systolic murmur .. "

19 I am suggesting to you that that is
20 not the best type of murmur to hear following this
21 type of procedure to install this type of shunt?

22 A. It indicates that the shunt
23 may not be as large as you would have liked, and that
24 there is not two-way flow.

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B.4

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Q. Precisely. Underneath that

reference you will see, on the next line:

"Seen by Dr. Izukawa ... "

whom we have heard here was the attending cardiologist:

"... who agrees with murmur."

Do you see that on the next line

underneath "only systolic murmur"?

A. I can read part of that; right,

"who agrees with murmur".

Q. Right.

A. Right.

Q. Now, I am suggesting to you that the evidence concerning that reference was that the patient was seen by the doctor, that there was concern about the shunt, and there was raised the possibility of reoperating and maybe revising the shunt by virtue of that murmur that they found troublesome. I take it that that entry there would accord with that view as you understand it?

A. I think it would be consistent with it, yes.

Q. And I take it that you will agree with me that in circumstances where you don't have a good shunt in a baby such as Stephanie Lombardo, you have a baby in whom you can get a sudden change?



B.5

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2 A. That is correct.

3

Q. And thirdly, if you will turn
4 the page; do you have in your Hospital record page 38A,
it was left out of the original record?

5

A. I have Exhibit 78A.

6

Q. That's it.

7

A. This is it?

8

Q. Yes.

9

A. Okay.

10

Q. And if I could direct you,

11

Doctor, to the second entry on that page under 21/12/80
12 day 5, that I understand is in reference to the fifth
day this child was in the Intensive Care Unit. Do you
13 see the reference there: "PTT's" all over the place?

14

A. Yes.

15

Q. And then there is reference
16 there following to certain of the values of the PTT's.

17

A. "Down to 24 again, her PTT
18 later was 71",

19

is that what you are referring to?

20

Q. That is correct.

21

A. Okay.

22

Q. I understand they were having
difficulties with the heparinization of this child,
23 and those partial thromboplastin times

24

25



B.6

1

2 confirm that as far as you are concerned?

3 A. Those are partial thromboplastin
4 times I guess. He doesn't have the normals, they
5 are always reporting them over the normal that was run
6 at that point in time, are those on another sheet
7 some place, you can't interpret the isolated time
without knowing what the control was.

8 Q. Well, I don't have that, Doctor.
9 The reference was to those entries and the fact that
10 there was trouble with the heparinization of this child
11 is that at least consistent with that?

12 A. They were having difficulty
13 apparently maintaining equal heparinization, or
14 coagulation with heparin I should say.

15 Q. And then the reference above
16 that is: "stable, looks blue most of the time", do
you see that?

17 A. Yes.

18 Q. This is - bearing in mind that
19 we know she died December the 23, 1982, this is two
20 days prior to her death, correct?

21 A. Yes.

22 Q. And the fact that she does look
23 blue most of the time may be consistent with the shunt
being of marginal operation?

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A. I think it would reflect that there was still an adequate pulmonary flow. You get the impression that it may have been - the flow may have been changing from time to time maybe depending on the cardiac output at the point in time. Her transfer note for example says that the baby looks quite pink, cyanotic when upset.

Q. Right.

A. And so she had some change in colour apparently from time to time depending on whether she was crying and so forth.

Q. That I think is really my point. We have a child whose condition is not exactly identical at all times.

A. At least her colour, her oxygenization wasn't identical at all times.

Q. And I am suggesting that having regard to the fact of her very young age; the fact that the murmur was perhaps indicative of the shunt being less than adequate; the problems with her heparinization; the fact that she did appear sometimes pink, sometimes blue. That there is a basis there for a more guarded view of her post-operative course than your characterization, which is stable?

A. I think stable is a relative



B.8

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2 term. I am not, I don't think I have any quarrel
3 with what you are suggesting. The fact that a baby
4 with a new shunt may still be partly cyanotic is not
5 particularly unusual, I mean that is not an infrequent
6 occurrence. The fact that her cyanosis might be more
7 or less at different times of the day may not
8 particularly indicate that she is unstable. The
9 fact that you are having difficulty getting the right
10 rate of heparin infusion and PTT's are changing simply
11 means you haven't found the right rate for that baby
12 yet. It may mean that when she is not adequately
13 anticoagulated that there is increased risk and in
14 that period of time that the shunt could develop a
15 thrombus, but I don't think it is change in colour.
16 She obviously is not well and stable is not equal
17 to well and she would be susceptibel to all the risks
18 inherent in a baby who had just had a shunt placed
19 and the shunt being inadequate in size. But stable
20 also can mean that her vital signs were stable.

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Q. All right. I think the

only point I want to make was that because as Mr.

Scott mentioned on more than one occasion lawyers

tend to be simplistic. I just wanted you to confirm

for us that your characterization of "stable" does

not necessarily mean out of the woods.

A. Oh, absolutely not.

Q. And as you have told us,

having regard to the picture presented in this record,
the shunt was open to a thrombus at any time.

A. I think that was a risk
obviously.

Q. And in any event one's
impression of her post operative course the fact that
death occurred or may have occurred as a result of
an occlusion of the shunt is a reasonable one?

A. Yes, I think it would - yes,
it was.

Q. And in terms of your
characterization of Stephanie Lombardo's death you
were swayed by the digoxin information? Correct?

A. That is correct.

Q. That ---

A. And the fact that I do not
have autopsy information to confirm the shunt one way



1

2 or the other.

3 Q. Right.

4 A. That would be extremely
5 helpful.

6 Q. And that fact, namely the
7 digoxin information as well as the autopsy information,
8 you acknowledge was not available to the clinicians
9 at the time?

10 A. That is correct.

11 Q. And their impression in its
12 absence you told us was reasonable?

13 A. Yes, I think it was.

14 Q. Now the second death in
15 terms of time with which I would like to deal, the
16 second one that you have characterized as being
17 reasonably probably likely due to digoxin poisoning,
18 is Baby Belanger, and that baby died I believe December
19 28, 1980.

20 Do you have the Hospital record for
21 that child? It is Exhibit No. 79.

22 A. Okay.

23 Q. Now again, and I am referring
24 to your report, Dr. Kauffman, Exhibit 266, it is
25 clear that is again in relation to Jesse Belanger
that a critical feature to your opinion concerning



1

2 that child is the digoxin information?

3 A. Yes, I think it was.

4 Q. Again having regard to the fact
5 there were positive findings for digoxin in a child
6 for whom it was not prescribed?

7 A. That is correct.

8 Q. And again, and I am going back
9 to the questions put to you by Miss Cronk in your
10 examination in chief, you were aware as given by
11 Dr. Rowe that the clinicians at the time felt that
this child's death was due to his general condition?

12 A. Did I ---

13 Q. I believe you acknowledged
that.

14 A. I think I probably did, but
15 I don't know what I actually said. Do you have the
16 reference there?

17 A. I think I do. I believe it is
in Volume No. 71, 5580.

18 MS. CRONK: I am not sure, your question
19 perhaps implies that the Doctor knew at the time that
20 he was assessing the case. He knew it when I told
21 him.

22 MR. ORTVED: Oh, okay. That is what
23 I was speaking of.

24

25



1

2 THE WITNESS: Which was your
3 question?

4

5 MR. ORTVED: Q. That Miss Cronk told
6 you of what the clinician's evidence had been concerning
7 his general condition being the cause of death and
8 that was something that you went on to say you felt
9 was consistent with what you saw in this child.

10 Right?

11 A. Yes, I agree with that.

12 Q. I just want to follow that
13 up very briefly in terms of the basis for that. I
14 would ask you to turn to page 58 of the record.

15 A. 58 of the Hospital record?

16 Q. 58 of the Hospital record.
17 You will see the entry at the top of the page, Dr.
18 Kauffman, "Cardiology, put on O2 abbreviated shunt
19 murmur".

20 A. Yes, I see that.

21 Q. And you will know better than
22 I, but I understand that the reference to abbreviated
23 shunt murmur is again a less than optimal finding
24 in a child in whom a shunt has been installed?

25 A. That is apparently according
26 to the little diagram they drew, the shunt was
27 producing a murmur for a shorter duration of systole



1

2 than they would have liked.

3

4 Q. Precisely. And that as I
5 understand it can indicate that the shunt is perhaps
6 too small but by the same token perhaps too large?

7

8 A. I can't respond to that. I
9 am not sure.

10

11 Q. All right. You will recall
12 in any event that when you reviewed this particular
13 Hospital record it revealed that rather than being
14 returned to the ward from the Intensive Care Unit
15 the child went to the Neonatal Intensive Care Unit.
16 Do you recall that?

17

18

B?

19

Q. Yes. On the seventh floor.

20

A. Yes.

21

22

23

24

25

Q. And then if you will turn to
page 62 of the Hospital record there is a note
referring to the transfer from 7G, the Neonatal
Intensive Care Unit to the ward. Do you see that?

A. Right.

26

27

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Q. And one of the references
concerning the condition of the child at the time
of his transfer down to the ward was in the second
last line, "Collapsed left lung".



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2 A. Right.

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25

Q. There are, as I understand it, having regard to the reference concerning respirations and the fact that the liver was somewhat extended, indications of possible early congestive heart failure?

A. Well, it was either - apparently it was unclear to them whether the liver was down because of congestive failure or the problem with the lungs, hyperexpansion of the lungs may be pushing the liver down. I got the impression they were not sure right then which was causing it, but the liver was noticed to be down further than they thought it should be.

Q. Do you agree in your review of the chart there was a concern about possible early congestive heart failure?

A. I don't recall that right now. I may have been aware of it at an earlier time. I don't see it on the chart.

Q. All right. You agree that in essence the finding concerning the liver may provide a basis for that?

A. Yes.

Q. For that impression?



1

2 A. Yes, it may be a sign of
3 congestive failure.

4 Q. Then I take it and I think
5 you confirmed this earlier, you recalled that on
6 autopsy there were findings consistent with a partial
7 Di George Syndrome in this child?

8 A. Yes.

9 Q. And you have told us already
10 that the terminal event was compatible with this
11 child's disease?

12 A. With the heart disease?

13 Q. Yes.

14 A. Yes.

15 Q. And you told us also that you
16 were taken by its suddenness?

17 A. Yes.

18 Q. I take it you are prepared
19 to agree that a Di George Syndrome can lead to that
20 sudden death?

21 A. I don't consider myself an
22 expert in Di George Syndrome, but from what little I
23 know about it it can be associated with sudden death
24 in infants.

25 Q. And so also having regard to
the respiratory difficulties experienced by this child



1

2 I take it that you agree with me that that type of
3 condition can pre-dispose a child to hypoxic
4 episodes, respiratory distress?

5 A. Yes. This baby apparently had
6 some atelectasis in his lungs, the upper lobes, which
7 means that some of the lobules or lobes of the lungs
8 weren't expanded with air, and in a baby who is
9 already compromised like this baby was in terms of
10 oxygenation, a decreased lung volume will make things
even worse.

11 Q. Again, and I am reviewing,
12 you were swayed by the objective evidence of digoxin
13 in this child?

14 A. That was an important piece
15 of information.

16 Q. Again that was a fact not
17 known to the clinicians at the time?

18 A. That is my understanding, yes.

19 Q. And their perception as to
20 the explanations for the cause of death is one that
21 is not without foundation having regard to your
22 analysis of the Hospital record?

23 A. Had I been there at the time
24 I can't say that I would not have come to a different
25 would not have come to the same conclusion they did.



1
2 D/BM/ak

3 Q. Right. Thirdly and finally
4 I would like to deal very briefly with the Estrella
5 child, Dr. Kauffman. I don't think you probably have
6 to have the record placed in front of you for this.
7 That is a death which occurred January 11th, 1981 and
8 that is a death which you have told us you were not
9 able to express an opinion as to whether or not it
10 was reasonably probably due to digoxin poisoning.

11 A. Yes, I agree with you.

12 Q. And I take it from your very
13 extensive review of this child and this child's death
14 are aware of its condition in the period prior to its
15 ultimate demise.

16 A. Yes.

17 Q. And I will particularize it
18 briefly, but I mean, this child was in very severe
19 distress. Would that be fair?

20 A. I think that is true. She had
21 very bad anatomical heart disease and she was suffer-
22 ing from progressive congestive failure that really
23 wasn't responding to medical management adequately.

24 Q. And was not only intractable
25 but was severe?

26 A. Yes.

27 Q. And her nutritional status was



D2

1

2

very bad?

3

A. I would agree with that from
what I saw on the chart.

4

Q. She had, in the period of her
last admission, experienced seizures, respiratory
arrest, some bradycardia, correct?

5

A. Yes.

6

Q. On autopsy there was positive
finding for pneumonia.

7

A. I don't remember that
specifically.

8

Q. All right.

9

A. But I haven't looked at the
autopsy report recently.

10

Q. All right, you don't quarrel
with that?

11

A. No.

12

Q. And certainly the pathology was
certainly adequate to explain this child's death
absent any digoxin.

13

A. I think just being presented
her case without any other corroborative information
I would conclude that her severe heart disease was
consistent with her dying some time during early in
life. You can't say when.

14

15



Kauffman, cr.ex.
(Ortved)

D3

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Q. Right. So, all of the other deaths to which you have assigned a rating of reasonably probably likely due to digoxin intoxication ---

MS. CRONK: Sir, I'm sorry, again, I don't mean to interrupt my friend but that is the fifth time that I have heard reasonably probably likely and I confess I have no idea what that means. I thought I did understand what the doctor had explained to be his categorization of these deaths. If Mr. Ortved thinks it means something else maybe it should be clarified. He's got me nervous, sir, it is early in the morning and I don't know what reasonably probably likely means.

THE WITNESS: I don't know either, that's why I chuckled a minute ago.

THE COMMISSIONER: Certainly not certain.

THE WITNESS: Certainly not certain, that is correct.

MR. ORTVED: I am not entirely happy with that wording myself but the only reason I am using it is because you used it, so, that is why I decided I would adopt it.

THE WITNESS: Did I use them altogether in that sequence?



D4

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2

MR. ORTVED: Q. That's what I

3

understand.

4

A. Can you point me to that?

5

Q. Let me just find the reference.

6

It is 5868.

7

THE COMMISSIONER: What volume now,
please?

8

MR. ORTVED: 5868 and of course I
don't have the volume. But it's probably 70 - no,
71.

11

THE COMMISSIONER: No, it is 72.

12

MS. CRONK: 72, sir.

13

MR. ORTVED: You're right, 72.

14

THE COMMISSIONER: 5878?

15

MR. ORTVED: 5868.

16

MS. CRONK: Reasonable probability
is the language I see.

17

THE WITNESS: 5868?

18

MR. ORTVED: Now, you are not going
to tell me that is different?

20

MS. CRONK: Well, maybe it is.

21

MR. ORTVED: Well, that is what I
was trying to incorporate in my question. Let me
just read the reference to it.

23

THE WITNESS: I think what I said was

24

25



D5

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a little better grammar than reasonably probably
likely.

4

MR. ORTVED: Okay. Well, you are the
boss.

6

THE WITNESS: Who are we talking about
here at this point?

7

MR. ORTVED: Q. Just so that we
understand one another, Doctor, let us read the
evidence. This is at Volume No. 78, page No. 5868:

10

"Obviously, Doctor, there are without
showing any particular brilliance at
this time of day,..."

11

Now, that may have been before 10:00 too, Doctor.

12

"...Doctor, three ratings within those
two extremes. May we fairly infer
from the ratings which you have outlined
on page 3 of this letter that any death
with the rating of 3 or more in
your judgment was a case where there was
a reasonable probability that death had
resulted from digoxin intoxication?

13

A. There was certainly a possi-
bility, and I suppose you could call it
a reasonable probability, yes.

14

Q. 3 or more?

15

16



D6

1
2 "A. 3 or more. I would certainly
3 agree that those with ratings 2 and 1
4 I really considered a very low probability,
5 and I am not sure that realistically
6 I can differentiate between 2 and 1,
7 but I had to use up the numbers."

8 And I understand now why Miss Cronk
9 was upset because it was her words I was torturing
10 and not yours. The deaths which I want to deal and
11 I hope I have been dealing are those in the case of
12 Belanger and Lombardo where you felt there was a
13 reasonable probability of death due to digoxin
intoxication.

14 I am suggesting to you, and I don't
15 think there is any issue about this, that all of the
16 other deaths to which you assign that category 3 or
17 more, namely, a reasonable probability of digoxin
18 intoxication, 5 in number, occurred in March of 1981;
agreed?

19 A. I wasn't aware of that.

20 Q. All right.

21 A. But I wouldn't argue with you.

22 Q. Well, the other five are Hines,
23 Miller, Inwood, Pacsai and Cook and will you take
24 it from me for the moment that those all occurred in

25



1

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March of 1981?

3

4

A. I will accept that unless
somebody else corrects me.

5

6

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Q. Right. They sure will if I'm
wrong. That being the case, looking at all of the
deaths you reviewed, and you have told us the 37 and
40 deaths respectively that I know are the same, but
having regard to all of the deaths that you reviewed
up to March of 1981, the only ones that you are
prepared to say that there was a reasonable probability
of death due to digoxin intoxication, namely, Lombardo
and Belanger, that there was an acceptable basis for
an alternative view, correct?

14

A. At that time?

15

Q. Right.

16

A. Not at the time I reviewed it

17

but at the time they died.

18

Q. Precisely, absent the digoxin
intoxication.

19

20

A. Absent the subsequent informa-
tion.

21

22

Q. Precisely, there was a reason-
able basis for an alternative view.

23

24

A. Yes.

25

Q. And the alternative view was,



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namely, not homicide but death due to natural causes.

3

4

A. Or complications of their underlying illness I would say.

5

6

7

Q. Right. And the critical fact upon which your opinion turns is the digoxin data in respect of those two children which you acknowledge was available much later.

8

9

A. Yes.

10

11

12

Q. Now, what I want to do next, Dr. Kauffman, is just analyze briefly your respective reports in relation to the report to Mr. Wiley and the report to the Centers for Disease Control.

13

14

As I understand it, in the report to Mr. Wiley you analyzed 40 cases.

15

16

17

A. I looked at information, not charts on all of them, but I looked at information on some additional cases more than 40, but I really focused on some less than 40.

18

19

Q. All right. Well, I think I will have to ask you to clarify that.

20

21

22

23

24

A. Well, in my second letter I believe I indicated - maybe I'm wrong - no, I'm sorry, it is not in this letter. At some point I thought I had indicated that I reviewed case summaries and any other information that was provided to me on a larger

25



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3 number of infants, but the ones I really reviewed were
these in the 35 to 40 cases that we are talking about.

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THE COMMISSIONER: At the very

beginning of your first letter, your first report, you say that you have reviewed approximately 40 deaths and has included a review of case summaries as well as a review of the original charts of 30 of the cases.

THE WITNESS: Right, okay, that is

correct.

THE COMMISSIONER: And of course you

go on to specifically deal with 10.

THE WITNESS: Right.

MR. ORTVED: Q. The reference that

the Commissioner has put to you is the one that I have been going by and that's why I took the number 40.

A. The first letter, yes.

Q. Were there cases in addition

to the 40 that you reviewed however summarily?

A. I can't document it for you.

Now, I think I reviewed all of the case reports

prepared by Dr. Hastreiter which may have included some additional cases.

Q. That's right.

A. But I didn't spend much time

with them because there was really no pertinent



1

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digoxin data that was helpful to me, so, I didn't
focus on them.

3

4

Q. That's fair. So, you more or
less focused on 40 and you concentrated for the
purposes of your report to Mr. Wiley upon an analysis
from a pharmacologic point of view?

5

6

A. That is correct.

7

8

Q. Also bearing in mind the
clinical picture of those children as they presented.

9

10

A. That's right.

11

12

Q. And you were able to determine
that there was objective evidence providing a basis
for an expression of opinion on your part in 10 of
those cases?

13

14

A. I think that was correct.

15

16

Q. And that is to say, and this
is about the extent of my mathematical ability, there
are 30 cases in which you weren't able to express
such an opinion; 30 of the 40.

17

18

A. I think that I indicated I
didn't have enough information to really express an
opinion, yes.

19

20

Q. Right. And that would be in
30 of the 40?

21

22

A. Yes. I don't know if it was

23

24

25



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exactly 40, I said approximately 40.

3

Q. All right.

4

A. But it is approximately 40.

5

Q. And that is to say that
objectively, to use your words, and I hope I am being
fair that there was no objective evidence of digoxin
toxicity in those approximately 30 cases.

6

7

A. I think that is a fair repre-
sentation of my wording.

8

9

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Q. And in the 10 cases in which
you did feel competent to express an opinion, having
regard to the information available to you, in your
view seven cases supported an opinion that death
due to digoxin intoxication was a reasonable
probability.

A. Yes.

Q. Three did not.

A. I think that is correct.

Q. So, therefore, we have a

total of approximately 30 plus another 3. So,
approximately 33 cases in which there is no objective
evidence of death due to digoxin intoxication.

A. I just didn't have enough to
work with.

Q. Right. And as I guess it comes



1

2

3 as no surprise to any of us here, that analysis and
4 those conclusions tie in precisely with your analysis
done for the Centers for Disease Control.

5

6 A. I don't think there are any
7 substantive differences; not that I intended it that
way because I did them independently at different
8 times and in different ways but it turns out that I
9 came to approximately the same conclusion both times.

10

Q. Happily?

11

A. Pardon?

12

Q. Happily?

13

14 A. Well, I was relieved when I
saw what happened when they showed me the tabulated
data later on. I didn't realize at the time I was doing
15 it it was going to turn out that way.

16

17 Q. All right. In any event, in
the analysis you did for the Centers for Disease
Control you looked at 37 children?

18

A. That is correct.

19

20 Q. And it was again the same type
of analysis, namely, from a pharmacological viewpoint
21 but taking into account the clinical picture, along
with the other data.

22

A. Yes.

23

24 Q. And there you were asked to

25



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2

3 assign numbers about which you have told us you had
4 these reservations, and I won't go into those. But
5 we have now canvassed the fact that in seven of those
6 cases, seven of the 37, you felt competent in applying
a number of 3 and up.

7

A. Yes.

8

9 Q. Namely, a reasonable probability
of death due to digoxin intoxication.

10

A. Yes.

11

12 Q. That is to say, 30 you assigned
one or two, namely, low probability of death due to
digoxin intoxication?

13

14 A. I think we added it up the
other day, it was 26.

15

16 Q. Well now, be careful because
17 if you look at 37 cases and you have assigned a 3 and
up to 7 of them.

18

19 A. Well, there are 36 that you
are concerned with here, one of them isn't a part of
this group of babies.

20

Q. Oh, all right.

21

22 A. So, there are 36 and then if
23 you subtract the 7 that you have alluded to from
24 those 36 you should get I believe the number, the
sum of those that were given either a 1 or 2 rating

25



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2

3 on the CDC scale. I haven't added this up but I think
4 that would be the way it would come out. Do you
have the summary sheet there?

5

Q. It should be 29, shouldn't it?

6

A. You may be right.

7

Q. I mean, my mathematics isn't

8

the greatest but 36 minus 7 comes to 29.

9

10

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DM.jc
E

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2 THE COMMISSIONER: We are now - I think
3 you are referring to Exhibit 275 which is your criteria.

4 THE WITNESS: Right.

5 THE COMMISSIONER: For the rating,
6 and that is - but those were in Group 1, but we also
7 have --

8 MR. ORTVED: Group 2.

9 THE COMMISSIONER: Group 2.

10 MR. ORTVED: Right.

11 THE WITNESS: If you subtract Group 1
12 and Group 2 from the original 36 --

13 MR. ORTVED: Q. You get 29.

14 MS. CRONK: You get 7.

15 MR. ORTVED: Oh, yes, you get 7.

16 THE WITNESS: Yes.

17 MR. ORTVED: Q. That leaves 29 in
18 Groups 1 and 2.

19 A. I believe you are right.

20 Q. Okay.

21 A. And if you added one that we
22 are not considering here it would be 30.

23 Q. That is what I thought.

24 A. Okay.

25 Q. And we have the same 7 that
26 are given a 3, are the same 7 that you felt you could



E.2

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2 comment positively upon in terms of a reasonable
3 probability of digoxin intoxication, to Mr. Wiley?

4 A. Yes.

5 Q. And you went on to tell us
6 that of the 29 or 30 whatever in the 1 and 2 category,
7 you felt comfortable in stating that 20 of those, in
8 20 of those cases you can exclude the possibility of
digoxin intoxication?

9 A. I didn't say that. I don't
10 want you to misinterpret - you are talking about the
11 CDC Report now?

12 Q. Yes.

13 A. I don't want you to misinterpret
14 the implications of my rating. As I think I tried to
15 say the other day that if a baby received a low rating
16 from me it meant either way there was no pharmacological
17 information to, with which to value the case, or
18 there was information which indicated to me that it
was highly unlikely that digoxin intoxication existed.

19 Q. All right. Now, I just want
20 to co-ordinate your two respective reports, because
21 there is one or two cases that are not common, and I
am not going to go into them in detail.

22 For instance, in your CDC analysis,
23 you have told us that you assigned a 2 to both Babies

24

25



E.3

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2 Gage and Baby Gionas; is that correct?

3 A. I think that is correct.

4 Q. And you explained to us, on

5 Wednesday last, your basis for assigning a 2 to those
6 children, and believe me, Mr. Commissioner, you may
7 rest assured I won't go through that again.

8 You also stated, and it is at page
9 5905.

10 A. Of Volume 72?

11 Q. Of Volume 72, when Miss Cronk
12 then went back over the ratings assigned to Babies
13 Gage and Gionas and you concluded by saying:

14 "I should say that while I am doing
15 the search I really viewed the
16 rankings of 1 and 2 as being children
17 with which there was very little
confidence that digoxin was indeed
related to their death."

18 Correct?

19 A. That is correct, I don't see
20 where you are reading but I agree with you.

21 Q. Volume 72, it is the last
22 sentence on page 5905.

23 A. Okay.

24 Q. And you also told Miss Cronk

25



E.4

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2 in reporting to Mr. Wiley you did not include Babies
3 Gage and Gionas because you felt there was insufficient
4 data on which you could relate to their deaths?

5

A. That is correct.

6

Q. 2 you also assigned to Baby
Estrella?

7

A. Eventually, yes.

8

Q. And you have explained that
rationale in your report to Mr. Wiley and I don't
intend to canvass that again. Then if you could look
to Exhibits 273 and 274.

12

A. Are those the tabulations of
the --

13

Q. I think Mr. Elliot has those
out for you.

15

A. Okay.

16

Q. You have in those two exhibits,
Dr. Kauffman, in the summaries under "Cause of digoxin
intoxication" for Janice Estrella --

19

A. You are talking about 273?

20

Q. I am talking about both.

21

A. Okay.

22

Q. Let us talk about 273 first;
under "Cause of digoxin intoxication" opposite Janice
Estrella you have:

24

25



E.5

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3 do you see that?

4

A. Right.

5

Q. And so also on Exhibit No. 274,

6

Dr. Kauffman, opposite Janice Estrella, under the
heading: "Cause of digoxin intoxication" you have:

7

"Acute Event - single overdose",

8

correct?

9

A. Right.

10

Q. That is a reflection of what

11

appears in your rating sheet in Exhibit 272?

12

A. That is correct.

13

Q. But as I understand it Janice
Estrella, which is in my package here the No. 02044,
it appears to me that your selection of: "Cause of
digoxin intoxication", "Acute Event - single overdose",
was likely made at the same time that you assigned a
5, namely on the first run-through of that case,
would that be correct?

19

A. That is correct. And when I
received the additional information and changed the
rating I did not change the other parts and so that
is in error.

22

Q. That is what I was going to
say.

24

25



E.6

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2 A. Yes. I neglected to change
3 the comments. I changed the comments portion on none
4 of the ones that I called and changed the rating on.
5 So the comments reflect my original evaluation based
6 on an erroneous assumption of digoxin only.

7 Q. So if today we were to be
8 running through your rating sheet in relation to
9 Janice Estrella, I take it, and I am actually going
10 by your rating relation to the Gionas child, your
11 probable selection under "Cause of Digoxin Intoxication"
12 would probably be what "Not Applicable"?

13 A. You are on the second page?

14 Q. Yes.

15 A. Did digoxin intoxication appear
16 to be the result of?

17 Q. Yes.

18 A. I would probably have either
19 scored it "Unable to Determine" or "Not Applicable".

20 Q. Having regard to the fact
21 that you indicate that you really can't conclude with
22 any likelihood, with any certainty that the child was
23 overdosed with digoxin "Unable to Determine" may not
24 be as applicable as "Not Applicable", would you agree
25 with me?

26 A. I would agree with you.



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Q. And I think "Not Applicable" is probably a better category having regard to, for instance, your application of that term to the Gionas child, which as I understand it, the cases really having regard to your analysis, were not so different.

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A. They were not identical, but in looking at them in the overall context and having to take into consideration the problems with the Estrella post mortem sample, I would not distinguish them on the basis of those criteria.

Q.

So while Exhibits 274 and 273 are an accurate reflection of what appears in Exhibit 272, in terms of your present opinion the entry opposite Estrella should probably read, I am suggesting, "Not Applicable".

A. I would revise that, yes.

Q. Thank you.

A. Today I would.

Q. The only other cases that are

not common to your reports to Mr. Wiley, to the Centers for Disease Control are Woodcock and Onofre, upon which you felt unable to report to Mr. Wiley, but you explained why you couldn't express an opinion and that is reflected in the Centers for Disease



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Control report where you assigned No. 1, correct?

3

A. That's correct.

4

5

6

7

8

9

Q. Doctor, I spoke to you just briefly last night and you indicated, as I understood to be the case, that post morten digoxin analysis is not a common place event in hospitals in North America today other than the Hospital for Sick Children, would that be correct?

10

A. I think what you asked me was, did we do it routinely in our Hospital and I said, no.

11

12

13

Q. Yes. And as I understand it your Hospital is reflective of other hospitals on the Continent, other than the Hospital for Sick Children?

14

15

16

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A. I don't know how reflective it is. I don't know what happens, what the policy is at other children's hospitals, I know I wouldn't compare it to other general hospitals. It is a tertiary referral children's hospital associated with the University, and in that way it is comparable to the Hospital for Sick Children, and it is comparable to a number of other children's hospitals in North America. In terms of what other children's hospitals policies are about doing toxicology studies routinely at autopsies I have no idea. I can tell you that digoxin measurements are not routinely done at autopsy



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in our hospital.

3

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Q. This is a subject about which I thought you would probably be more knowledgeable than I, maybe you say you are not. It is my information that routine post mortem toxicology analysis, and in particular analysis in relation to digoxin are not done in hospitals in this Continent save and except for the Hospital for Sick Children, do you disagree?

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A. I think I can answer that in general. I think that it is impractical to do a full toxicological workout on every autopsy, it is just not practical. So in my experience toxicology evaluations have usually been done for patients in whom there was some reason to believe it might be useful as a part of the autopsy. If you were going to do routine drug assays, how would you know which one to choose anyway?

26

Q. That was going to be my next question.

27

A. I don't know how, if I was,

say we were going to routinely do drug assays in

autopsies, I would just - open ended like that, I

would not know where to start unless you did a

complete toxicologic workout and that is inordinately



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expensive.

3

Q. And impractical?

4

A. Pardon?

5

Q. And impractical?

6

A. It's impractical because of
the time and resources involved.

7

Q. Precisely. Yet as you have
also been very fair in confirming for us, in the
absence of - for instance, a post morten test for
digoxin, it is very difficult to say whether a
particular death may or may not be due to digoxin
intoxication; or in a cardiac patient underlying
heart disease.

14

A. Unless you have documentation
that an overdose did indeed occur.

15

Q. Well obviously, but absent
that.

17

A. But absent that, particularly
if the child was never known to have been given
digoxin therapeutically, I wouldn't think one would
particularly suspect it unless there were other
extenuating circumstances to suggest it.

22

Q. And I take it that you as a
pediatrician responsible for patients in a children's
hospital look upon all of this; if in fact a murder

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3 occurred with a quality of "There but for the Grace
4 of God go I".

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10 A. I don't know how to respond
11 to that question. Obviously we never want adverse
12 things to happen to our patients. I am not too sure
13 what you are implying, but we all run a fair amount
14 of risk when we practise medicine. Part of it we
15 think coming from your profession, but I won't pursue
16 that.

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Q. My only point is this, if in
fact there were deliberate overdoses of digoxin
administered at the Hospital for Sick Children,
Dr. Kauffman, which you feel was a reasonable
probability in at least seven cases.

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2 Q. Right. If that occurred
3 assuming it were intentional for the moment it is
4 the sort of thing that could strike anywhere?

5 Correct?

6 A. I think I would have to agree
7 that any institution is susceptible to that kind
8 of activity. For example, regardless of the careful
9 precautions we take we have had things happen like
10 babies admitted for child abuse actually sustaining
11 broken bones in the Hospital under our care because
12 a visitor mistreated them no matter how hard we tried
13 to protect them. So I think we are always susceptible
14 to some bad behaviour by somebody if such people
15 decide to do something.

16 Q. And the distinction between
17 intentional overdose of a drug digoxin, if in fact
18 that occurred, and additional abuse to a previously
19 abused child, the overdosing of digoxin may remain
20 masked having regard to its very mimicking symptoms
21 for a longer time?

22 A. I think that your level of
23 suspicion would be much lower in the case of digoxin
24 you describe. I assume you are talking about patients
25 that we are considering here, patients with severe
heart disease who are relatively high risk because of



1

2 their condition and have symptoms that could be
3 compatible with a number of things.

4 I think it would be less easy to
5 discern under those conditions what the cause was
6 than if you had a child who you know you had admitted
7 because you knew they may have been abused and so
8 you were watching carefully, and if something as
9 obvious as a fracture occurs you know that it has
indeed occurred.

10 MR. ORTVED: Thank you very much,
11 Doctor.

12 THE COMMISSIONER: Thank you, Mr.
13 Ortved.

14 MISS SYMES?

15 CROSS-EXAMINATION BY MS. SYMES:

16 Q. Dr. Kauffman, my name is
17 Beth Symes and represent the Registered Nurses
18 Association of Ontario and 38 individual nurses who
are involved in this case.

19 Dr. Kauffman, I gather that when you
20 were retained by the Police and by the Crown Attorney
21 prior to August of 1972 you had no prior knowledge of
the cases?

22 A. I had a very vague knowledge
23 that something unfortunate had happened at the

24

25



Kauffman, cr.ex.
(Symes)

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2 Hospital for Sick Children but I knew nothing beyond
3 that.

4 Q. Did you know, for example,
5 that a nurse had been charged with murder of four
6 of those children?

7 A. No, I did not until I arrived
8 in Toronto and was provided - that was among a lot
9 of other information. I think I actually became
10 aware of that when I read the Vanek - I don't know
11 the name of the document.

12 Q. Reasons for Judgment?

13 A. Yes, Reasons for Judgment.

14 Q. And when did you receive those?

15 A. I don't remember, but it was
16 some time - I think those were sent to me shortly
17 after my first visit to Toronto.

18 Q. So you would have had the
19 Reasons of His Honour Judge Vanek before you did
20 either the Police Report or the CDC rating?

21 A. Yes. I reviewed a lot of
22 background information prior to that.

23 Q. And I gather that when you
24 attended that meeting on August the 27th, 1982
25 here in Toronto you knew that the Police were
investigating homicide?



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2 A. Yes, I did.

3

4 Q. And that you were going to be

part of the ongoing investigation?

5

6 A. Well, I didn't realize I was
7 going to be a part of an ongoing investigation. I
8 wasn't sure at that point what I was going to eventually
9 do. Had I known I probably would not have come.

10

Q. Nevertheless when you committed
11 yourself it became quickly apparent that in fact you
12 were part of an ongoing investigation?

13

A. I was aware quickly that I was
14 going to be asked for expert medical advice that would
15 be used in making decisions about an investigation.

16

Q. And we know that there was
17 a meeting on September 13th of a number of people
18 who were present at the August 27th meeting, and
19 we know - we have had as an exhibit, Exhibit 261,
20 the fact that minutes were kept of that meeting of
21 September 13th, 1982.

22

Were you invited to that meeting?

23

A. I don't remember for sure,
24 but as I ---

25

Q. You didn't attend the meeting
26 apparently?

27

A. No, as I recall I was asked

28



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2 to attend and I had a conflict and I did not attend.

3 Q. Dr. Kauffman, did you ever
4 see those minutes?

5 A. No, I did not.

6 Q. At any time?

7 A. At any time. This is the
first time I have seen them and I haven't read them.

8 Q. I gathered that you said
9 that ---

10 A. I never did see any minutes
11 of any of those meetings until this hearing this
12 week.

13 Q. Were you informed of the
contents of the meeting of September 13th by anyone?

14 A. No.

15 Q. You said that you had had
16 Dr. Hastreiter's case summaries to assist you in
17 your work?

18 A. That is correct.

19 Q. And did you have his case
summaries before you came up to Toronto on November
20 19, 1982, to do your chart review?

21 A. Yes, I did.

22 Q. Were you aware of his opinion
23 with respect to the cause of death then of the babies?

24

25



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2 A. To the extent that at the
3 bottom of some of the forms he had checked a poor,
4 good, fair, good or something like that. I didn't
5 pay much attention to that because I immediately
6 disagreed with some of them so I just discarded that.

7 I may have picked up something from
8 that but I don't consciously recall paying any
9 attention to those scores. Other than that I was
not aware of his overall opinion.

10 Q. Were you aware ---

11 THE COMMISSIONER: Excuse me, his
12 case summaries?

13 THE WITNESS: Yes.

14 THE COMMISSIONER: Are they the case
15 summaries that we have?

16 MS. CRONK: What has been referred to
17 as Dr. Hastreiter's report.

18 THE COMMISSIONER: Yes.

19 MS. CRONK: It is in fact a compilation
20 of individual case numbers.

21 THE COMMISSIONER: Well, did he have
22 some sort of code on those?

23 THE WITNESS: May I show you what I
24 was referring to?

25 THE COMMISSIONER: Yes. We can't have



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2 a private conversation. It is against the rules,
3 but you are saying ---

4 MS. CRONK: If you look at Exhibit
5 264 which has been marked before you, you will see
6 at the bottom of each individual child's sheet a
7 space for categorization as to probability of massive
digoxin overdose.

8 The categories are small, fair and
9 good.

10 THE COMMISSIONER: Where are these?

11 MS. CRONK: At the bottom of each
12 child's sheet. Pick any child and on the bottom of
13 the cover page for that child ---

14 THE COMMISSIONER: Oh, yes, I see it.

15 MS. CRONK: You will see the
16 categorization.

17 THE COMMISSIONER: Yes, I see it.

18 Thank you.

19 THE WITNESS: That is what I was
20 referring to.

21 THE COMMISSIONER: Exhibit 264.

22 MS. SYMES: Q. You had those then
23 before you came here on November 19th, 1982?

24 A. That is correct.

25 Q. And before you came on November



1

2 19th, 1982 did you know - had you had any discussion
3 with either the Crown Attorney or the Police as to
4 which of the 36 babies were in their opinion
5 suspicious or most suspicious, whatever terminology.

6 A. I had asked them to facilitate
7 my review and to make most efficient use
8 or my time which ones they would like me to review
9 in detail first, and in that sense they gave me a
list of 8 or 10 that they wanted me to look at.

10 Q. Most particularly?

11 A. Yes.

12 Q. You told us in fact you
13 divided that single day not equally amongst 36?

14 A. No, I am not talking about that
15 day, I am talking about earlier. Early on I talked
16 with Mr. Wiley and some of the police staff and I
17 asked them for some - because we had a large number
18 of babies and I said give me some priority list and
19 I will look at those first. And so I got a list of,
20 I don't remember how many, but 8 or 10 babies that
21 they wanted me to look at first.

22 Q. If I look at Exhibit 273,
23 it is one of the summaries that Commission Counsel
24 has prepared of your gradings.

25 Dr. Kauffman, do those babies that



1

2 you were to look at those particularly all appear on
3 273?

4 A. . . I suspect they do, but unless
5 I could find, dig out that handwritten note and
6 compare them I couldn't tell you exactly with
7 certainty, but I suspect that they are among these
8 36 babies listed here, yes.

9 Q. Do you have them with you?

10 A. I may have and it will take
11 me a while to dig. I can look for it - I would be
12 willing to look for it if you wish.

13 Q. Could I ask you if perhaps
14 you do have time at the break, but I would ask you
15 from your memory are the 8 that you were - it was
16 either 8 or 10?

17 A. Yes. I don't remember for
18 sure.

19 Q. Were all of those in ratings
20 2 to 5 inclusive?

21 THE COMMISSIONER: I have a problem.
22 I understood this is what Mr. Wiley wanted you to
23 look at and this really has nothing to do with the
24 Atlanta Report. I would have thought that the
25 appropriate question is are those the babies that are
included in your report to Mr. Wiley?



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2 MS. SYMES: Well, I don't know that
3 and I just want - I just used 273 as a relatively
4 handy list of the children involved.

4

5 THE WITNESS: I would really rather
6 answer these questions for you accurately and see
7 if I can find some documentation to give you an
8 accurate answer before I respond.

8

9 MS. SYMES: Could I just leave that
10 then?

10

A. Yes, let's come back to it.

11

Q. And if we have our 20 minute
11 break I will ask you ---

12

A. Right. I would be happy to do
13 that.

14

Q. Dr. Kauffman, have you ever
15 before in your career participated in a rating of
16 clinical records on the basis of pharmacological
17 evidence?

18

A. Not in the way I did it this
time, no.

19

Q. Have you ever before been
20 part of an epidemiological study?

21

A. I am not an epidemiologist.

22

Q. No, I am sorry, have you ever
23 acted as a consultant in epidemiology?

24

25



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2 A. Yes, I have.

3

Q. And have you ever ---

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A. I have submitted - I shouldn't

5

have answered no to your previous question.

6

I recall now a few years ago I was a
7 consultant to a researcher in Rochester, New York,
8 and I was asked to review a whole series of cases
9 that had to do with medication administrations by
mothers, and I did a rating like this and then it
10 was used in an epidemiologic study so I guess I had
done it before.

11

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Q. And other than that have you
13 participated, for example, in rating children for
14 general statistical studies? Epidemiology indicates
disease, doesn't it, or trends. How about just a
15 straight statistical study?

16

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A. Well, I use statistics all
the time.

18

Q. Have you ever done ---

19

A. You mean ratings?

20

Q. Where you made ratings based
on your clinical judgment?

21

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A. Well, I have published papers
on pain and I used rating scales to assess pain.

23

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Q. All right. So then you would

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2 be familiar then and would have participated in other
3 research models, other statistical models?

4 A. Yes, I think I could agree
5 with that.

6 Q. Now in this particular case
7 you were I gather not blinded to the names of the
8 children?

9 A. That is correct.

10 Q. And I gather that an ideal
11 model would be that you not know the name?

12 A. I think if I were designing
13 this whole study perspective I would have rated
14 them blindly. Unfortunately we didn't have that
15 luxury.

16 Q. And the reason I gather for
17 the blinding of the charts or the blinding of you
18 with respect to the names on the charts is to make
19 sure that your evidence is not in any way biased or
20 influenced by previous information?

21 A. That is correct. If you could
22 do it that way that would be the goal.

23 Q. I gather you were also not
24 blinded as to the date of death?

25 A. That is correct. In fact that
26 was a piece of information I had to have available to



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1 me to make my assessment.

2

3 Q. Well, would it have made any
4 difference if you had been ---

5

6 A. Oh, you mean the date at which
7 I see what you mean. The date at which this
particular individual ---

8

Q. Yes, died.

9

A. No, I was not blinded to
that.

10

11 Q. And would you agree with me
12 that that is in an epidemiology study a good
characteristic to try to build in?

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A. You mean the blinding?
Q. The blinding.
A. I think if you are designing an ideal epidemiologic study you want as much blinding as possible to avoid inadvertent bias.

Q. Now, I gather that you were not given your criteria on which to design your observations, that all you were asked to do is use 5 as the greatest degree of probability and 1 as the least degree of probability and Atlanta left it up to you completely what criteria you defined 5 to be, 4 to be, et cetera?

A. That is correct.

Q. And I gather that you have said you had no discussions with the other two consultants who were doing the same process on the same children?

A. Well, they were doing a rating but with very different data.

Q. I quite agree. But I mean, they were trying to rate the children?

A. They were trying to rate the children with different criteria from a different perspective and, you are correct, I had no contact or discussion with them.



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Q. In fact, one of them you said
you still haven't talked to today.

A. I have never talked to either
of them.

Q. All right. So, you have no
idea then, I would presume, whether or not the
standards that you set for 5 correspond to the standards
that the other two set for 5.

A. I don't see any reason why they
would. I mean, it is apples and oranges. I was
using a different scale, a different approach. In
fact I think under the circumstances it would not have
been good for us to attempt to correspond or attempt
to relate them.

Q. No, but would you agree with
me that when you define Category 5 it may have had a
range of probability of, you know, so much, whereas,
someone else may have defined 5 as a wider one and
someone else may have defined it even narrower.

A. Oh, I agree with that and I
looked at this carefully. I suspect that all three
consultants did not agree on various cases and that
is what I would anticipate.

Q. Exactly. Not only might they
put different cases into Category 5, sir, but mightn't



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G3 we also have that the three consultants had different
3 categories 5?

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A. I'm not sure I am understanding
what you are saying.

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Q. In terms of width or broadness
or narrowness of category.

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A. I think if I understand what
you are talking about, any time you use a parametrics
scale, unless you have digital measureable data you
don't ever know for sure whether the range between
one digit and the next is the same as the range
between the next two digits and that is true with
I think any subjective rating scale that is used.
This is, for example in the pain situation I alluded
to, this has been debated for years in the literature.
If we use a linear pain score scale, is a pain index
of 4, the change in pain between 3 and 4 is the same
as between 1 and 2 and nobody knows. Is that what
you are alluding to?

Q. Well, the one point is that
the categories are not equal. That is exactly what
you have said.

A. They are not equal qualitatively
or quantitatively.

Q. Exactly. And similarly when



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we compare 5, the Category 5 of the three consultants
there is no reason to assume that in the abstract they
are the same categories.

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A. I haven't seen the other
consultant's criteria or scoring but I would in the
abstract agree with you.

8

9

Q. And in this experimental design
there was no attempt to make them all equal?

10

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A. No. In fact, I think there was
a conscious attempt to not make them equal, to not
compare them and have them done independently.

12

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Q. But there was no attempt by
the designer of the experiment to assist you in, say,
what type of cases should go into 5, for example.

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A. No, and I think it would have
been inappropriate for them to do so.

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THE COMMISSIONER: But with everybody
5 was the top.

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THE WITNESS: Well, to that degree
they told me 5 was the top of the scale and 1 was the
bottom of the scale, but I had no guidance one way
or the other as to how I should distribute the scale,
whether it should be linear, logarithmic or whatever
and as to the criteria I should use to assign patients
to any part of the scale.



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THE COMMISSIONER: Yes, Miss Cronk.

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MS. CRONK: Sir, I hadn't risen earlier because I thought Miss Symes would be reaching this and I may be anticipating her, but as you know, the expurgated version of the Atlanta Report has been marked, Exhibit 270, and it is quite clear I suggest on a reading, particularly of pages 11 and 12. If we turn for example simply to Dr. Nadas' approach, and there may be no magic in this, but I am not aware that any particular numerical ranking scheme applied to the assessment that he was asked to make.

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Certainly his criteria and breakdown is described at pages 11 and 12. It doesn't appear to approach in any sense the kind of ranking exercise that Dr. Kauffman went through. So, it is a little inappropriate perhaps to suggest there was a similarity in a gradation of 5, 4, 3, 2, 1 amongst all the consultants.

THE COMMISSIONER: Well, there was

a similarity in the sense that 5 was the most probable, to the least.

MS. CRONK: Well, what I'm suggesting

to you, sir, is that is not the exercise that Dr. Nadas went through at all, in my reading of the report. If you take a look at the assessments that he made



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3 and the scorings he made, they didn't have to do with
4 probability of death caused by digoxin intoxication
5 in the same sense that Dr. Kauffman's did.

6

7 THE COMMISSIONER: No, but improbability
8 of death from natural causes, did they not?

9

10 MS. CRONK: Well, sir, and again I
11 don't want to argue the point, we haven't heard from
12 the authors of Atlanta yet, but if you look at the
13 bottom of page 12, for example, that is where
14 Dr. Kauffman's rankings are set out.

15

16 THE COMMISSIONER: Yes.

17

18 MS. CRONK: But if you turn back to
19 page 11 you see at the bottom of the page the criteria
20 for assessments used by Dr. Nadas and I suggest they
21 are very different.

22

23 THE COMMISSIONER: Page 11?

24

25 MS. CRONK: The bottom of page 11
and the top of page 12. Do you see what I'm saying?

26

27 THE COMMISSIONER: Well, I think we
28 can leave this for argument anyway.

29

30 MS. SYMES: Q. But that is exactly my
31 point isn't it, Dr. Kauffman, that there was no
32 attempt to make sure that you were, when you did your
33 pharmacologic review, trying to assess things into
34 similar categories as the other two consultants?

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A. Well, I can't speak for the other two consultants and I can't speak for the people, the epidemiologists who did this. I simply was asked to do a specific thing in a specific way and I did it and I can't comment for you beyond that, you will have to ask the people who did it.

8

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Q. But I gather you did it without consultation with the other people, the other two consultants?

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A. Absolutely.

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Q. And you did it without

consultation with the Atlanta people in terms of

the design of what went into 5, 4, 3, 2, 1.

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A. In terms of the criteria.

15

Q. In terms of the criteria.

16

A. I wrote those myself.

17

Q. Exactly. Now, one of the

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things that you had said before is that, for example,

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in your pain study that the rating on a numerical

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scale of clinical observations is trying to fit

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information that might I guess not neatly fit into

22

5 discrete categories.

23

A. That is correct.

24

Q. And that the fitting or the pushing into a specific category is a human function

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2 based on judgment.

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4 A. I think to an extent that is

5 true, yes.

6

7 Q. For example, you said you had
trouble between 1 and 2 and you put some into 2. One
of the things was to use up the numbers.

8

9 A. Well, I said that facetiously.

10

11 Q. Yes, I understand.

12

13 A. But when it finally came down
14 to it I realized that there was probably no real
world difference between those two and I gather, I
haven't studied the CDC report, but I gather that
they came to the same conclusion and lumped all those
15 together anyway for all practical purposes.

16

17 Q. But when you are doing a rating
process such as the one you have done there is a
18 question of the degree of reliability in the placing
of a particular case in a specific category.

19

20 A. I think there is a real
probability of error we have talked about because of
the inherent variability in all of these cases, if
21 that is what you're asking.

22

23 Q. There is a variability in the
information and would you also agree that there is a
variability in the rater?

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A. I think that is true. That's why I said yesterday I didn't think I could go back and do the exercise again a year later and do it the same way.

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Q. Exactly. So, it is a process that you do the best job that you can at the particular time but if you did it at a different time you might do it differently?

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A. I might but I think you have to look - I didn't plan it this way but I think you have to look at the two exercises I did do at different times on different days in different ways and my overall conclusions, qualitative conclusions came out the same.

15

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Q. All right.

A. So, I apparently didn't change too much in that period of time.

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Q. Well, you were doing them after November 19th and I presume you finished by some time in January?

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A. Yes.

Q. All in the same period of time?

A. All what in the same period of time?

Q. All within the same two month



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period?

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A. The original - if you are talking about the police report, my original police report was written in late December.

4

Q. Yes, after you had examined the charts in November.

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A. Right. And then my revision, which was necessitated by additional information, was drafted in January, approximately a month after the December report.

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Q. Dr. Kauffman, were you asked to rate the same babies twice as a measure of your intercase reliability?

A. No, I rated them only once.

Q. In other statistical designs such as the one you did on pain, were you given the assignment of doing this, if blind, doing the same case twice to see if you agreed with yourself?

A. I wasn't rating the pain, I had a research nurse who was doing it. So that I wasn't the rater in that situation but she was blinded to what the patient was receiving for pain and we didn't have the opportunity in that particular study because of the nature of the patients to do simultaneous ratings but what we did do was do three different



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kinds of ratings at the same time on the patient.

3

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Q. But do you agree that one of the things that helps a design experiment is that if the rater, the single rater is asked to rate the same patient twice unknowingly to see if he is consistent?

5

6

A. I think that is ideal, yes.

7

Q. And do you also agree that it might be helpful that more than one rater rate the same child?

8

9

A. At least that would give you some competence as to the inter-rater variability.

10

11

Q. And that wasn't done in this case?

12

13

A. Not to my knowledge; if it was, I don't have that.

14

15

Q. You were the only pharmacologist?

16

17

A. To my knowledge nobody else did it but you will have to ask the people who designed the study.

18

19

Q. And I gather also when you were doing this rating that all of the babies that you did died; all of the babies that you rated died?

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A. I think that was the index system that got them into my pack.

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Q. But we know for example that some of the babies who were on that ward obviously with severe anatomical conditions at that time lived?

A. That is correct.

Q. And you weren't asked to rate those as a comparison or a qualitative check?

A. That is correct, but I am not sure how that would have - I would have to think about how that would have helped because the population from which we were sampling wasn't living babies.

Q. All right.

A. I think you are talking about two different populations from the universe. If one wanted to compare the underlying anatomical defects and the pharmacology of those children, based on the treatment they received, wouldn't it be a legitimate exercise to compare babies with the same anatomical problems, the same kind of treatment who lived with those babies who died?

A. I think if you were designing a perspective, ideal perspective controlled experiment that would be the way to do it.

Q. But it wasn't done in this particular case?

A. Well, we didn't have the luxury



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of designing a perspective from a controlled experiment.

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Q. I see. And when you were doing your ratings then, you knew then that you were rating the children who had died during the so-called epidemic period?

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A. Well, I was aware of the

epidemic period, yes, I didn't pay much attention to that but I was aware that that was how these babies, the babies that I was looking at were selected from a certain time to a certain later time. I really didn't take that into consideration in terms of my evaluations of them but I was aware that that is how they had been selected.

Q. And you were aware then that

they were being investigated by the police for homicide?

A. Well, I was aware that the

police were considering looking at them and considering whether or not they should proceed.

Q. And in addition, and we will

do it at the break, you knew that some of them were under special consideration and those you focused your attention on.

A. There was a small list that

they indicated to me was a higher priority to look at



1

2

initially. I wasn't restricted of course to looking
3 at all of them, in fact, I was asked to.

4

5

6

Q. Dr. Kauffman, do you have any
concerns that your ratings that you gave may have
been affected by this prior knowledge?

7

8

9

A. I think any time you have to
do a retrospective assessment like this that I have
concern for the reasons that you have suggested.

10

Q. I am not in any way saying ---

11

MR. YOUNG: Let the witness finish

12

his answer.

13

MS. SYMES: Would you let me just
complete it.

14

15

MR. HUNT: No, let him finish his
answer.

16

MR. YOUNG: Well, the witness hasn't
completed either, you asked the question and he
began to answer.

17

18

THE WITNESS: I think any time you
are forced to do a retrospective assessment, as we
were faced with here, that you have questions because
by nature a retrospective study is open to inadvertent
bias. You just can't control for bias, so, you can
never be sure that your error is randomly distributed.
There may be biased error. So, what I did was subject
to that, yes.

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Q. Exactly. I am not in any way quarrelling or casting aspersions on what was obviously a best effort to do that, but I guess we will accept that you do not have a bi-camera mind that the information that you received from all sources, including the ones I have outlined, were present when you made your decision.

A. All of the digoxin data; all of the clinical data; all of the clinical laboratory data, I took that all into consideration.

Q. As well as the fact that the police were investigating these deaths?

A. Well to the extent that I was really aware of it. You know I had no conscious bias based on that, but I can't tell you that I didn't have unconscious bias because we are all susceptible to that.

Q. You had knowledge?

A. I had knowledge, yes.

Q. Now I would like to ask you about patient Cook. I would ask if you would first of all turn to his chart, and also Mr. Cimbura's report, which are 95A to F on Justin Cook.

A. I'm sorry, you said 95A to F?

Q. Our report from Mr. Cimbura --



1

H2

2 THE COMMISSIONER: They are all
3 together, I think you will find --

4

5

THE WITNESS: Oh, you are talking
about the report, you are talking about Mr. Cimbura?

6

7

8

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MS. SYMES: Mr. Cimbura's report.

A. Okay.

Q. I guess they are multiple?

A. Yes.

Q. We have marked them sub A through
F.

A. Okay.

Q. And patient Cook's chart.

First of all looking at 95, we see on the first page,
which is 95A --

A. I'm sorry, my pages are not
numbered apparently the same as yours.

THE COMMISSIONER: Take that if you
would and I will find another one.

MS. SYMES: Q. The report of
January 11, 1982.

A. Right, thank you.

Q. In Justin Cook's samples that
were done at the Centre for Forensic Sciences --

THE COMMISSIONER: Would you hang on
for a moment. Oh, yes. All right.



Kauffman
cr.ex. (Symes)

1

H3

2 MS. SYMES: Q. I have some questions
3 about the tissue samples that were done. We have T42
4 that the tissue in the jar reported to be a sample of
5 heart muscle, and that digoxin concentration was the
6 one that we are of course most concerned about 117
7 nanograms per gram of digoxin; do you see that?

8 A. Yes.

9

Q. We then move down to T43 in
which we have tissue from the lung, and that is 153
nanograms per gram.

10

A. Right.

11

Q. Significantly less, obviously.

12

Would you turn to the next page
please, also of patient Cook. We have a sample, we
have three samples from the heart. In T11 we have
first of all from the ventricle, and we understand
that that is 36 nanograms per gram, that is a mixture
of digoxin and digoxinlike substances. The concentra-
tion of digoxin is 8; do you see where I am reading?

13

A. Yes, I follow you.

14

Q. Left atrium we have a digoxin
concentration of 39 nanograms per gram of digoxin
and/or digoxinlike substances?

15

A. Yes.

16

Q. And in the septum we have 36

17

18

19



Kauffman
cr.ex. (Symes)

1

H4 2 nanograms per gram of a mixture of digoxin and
3 digoxinlike substances, and the concentration of
4 digoxin is 4 nanograms per gram.

A. Yes, I am following you.

5

Q. And similarly in the lung we
6 have a concentration of 32 nanograms per gram of
7 digoxin and digoxinlike substances, and the concentra-
8 tion of digoxin was 15 nanograms per gram.

9

A. Right.

10

Q. With the exception, Dr.
11 Kauffman, of T42, the digoxin as analyzed by Dr.
12 Cimbura in the ventricle, left atrium and septum of
13 the heart are all significantly lower, do you agree,
14 than the T42 one, they are completely out of line?

15

MR. HUNT: I think Mr. Cimbura
16 indicated that one was fresh and the other fixed.

17

THE WITNESS: Yes, I think there is
18 a good explanation for that and I took that into
19 account when I assessed the case.

20

MS. SYMES: Q. What is the explana-
21 tion?

22

A. To my understanding the T42
23 sample was fresh autopsy tissue from the heart
24 muscle; and the others had been stored in Klotz
25 fixative for some time prior to taking them out and



1

H5 2 assaying them. If you look down at the top of page
3 it says:

4 "Fluid surrounding the tissues. The
5 fluid is reported to be Klotz fixative
6 solution.

7 The fluid was found to contain

8 29 nanograms per millilitre..."

9 of this mixture again.

10 Q. Of digoxin and/or digoxinlike
11 substances?

12 A. Right. So I had no problem
13 with those differences that you pointed out.

14 Q. So that the concentration of
15 digoxin in the fixed tissues, which are 8, 4 and 15,
16 are straight digoxin?

17 A. Yes.

18 Q. Would you say that they are
19 a result of the leaching from the tissue into the
20 Klotz solution?

21 A. Well, you have a situation here
22 where apparently the heart and the lungs were dumped
23 into one bottle and left to sit on the shelf for
24 a while in the Klotz solution, so that the decrease in
25 concentration is probably due to a combination of
leaching as well as breakdown of the digoxin.



1
H6 2

Q. And in the --

3

A. I really paid very little
attention to those in assessing Baby Cook.

4

Q. You paid very little attention
5 to the fixed tissues?

6

A. To the fixed tissues because
7 I had other data that was much better than that, I
8 thought.

9

Q. Which was the T42?

10

A. And the serum concentrations.

11

Q. I am particularly interested
12 in the level of dixogin tissues in the questions I am
13 going to be asking you.

14

A. Okay.

15

Q. Now, I believe it was on the
16 first day beginning at 5516, and I don't think you
17 need to refer to it because it is very difficult to
18 do calculations in the air. When you did the calcula-
tions --

19

A. You are talking about my
20 testimony now?

21

Q. Yes, sir. -- calculation of
22 minimum dose of digoxin needed to produce --

23

A. I'm sorry, which page?

24

Q. Volume 70, page 5516.

25



1

2 A. 5560 or 5516?

3 Q. 5516.

4 A. 5516, okay.

5 Q. Dr. Kauffman, I am going to
6 in fact ask you if you would essentially do the
7 calculations again but I want to look at the samples,
8 the assumptions pardon me, that you used in coming
9 to your conclusions.

10 A. Okay.

11 Q. The first one is that this
12 baby I gather we agree got into trouble at 3:45 in
13 the morning. Would you refer then to the patient's
14 chart, and perhaps if we just go through the assump-
15 tions of what we know about this child.

16 A. Okay. I have the chart.

17 Q. On page 29 of the chart, which
18 are the progress notes, we know that this child then
19 got into trouble at about 3:45, is that right?

20 A. That is correct.

21 Q. And we know that a drug which
22 is charted as propranolol was given .4 millilitres or
23 milligrams, is it?

24 A. Millilitres.

25 Q. -- millilitres at 3:45.

A. 3:45.



1

2 Q. And another dose of propranolol
3 was administered --

4 A. Right.

5 Q. -- at 3:55. If we go back
6 in fact to 27 we will see that in fact Dr. Kantak
7 is the person that we got the exact dose from, that
8 is the middle of the page, and you have referred to
9 that already. Initially he was given 0.4, this is
10 of Inderal; are you back on page 27 in the very centre
11 of the page?

12 A. Right.

13 Q. -- was given 0.4 millilitres
14 to which he did not respond, and then another 0.2
15 millilitres was pushed, and we gather that was pushed
16 some five to ten minutes later. So he would have had
17 the administration of the drug, which I guess totals
18 0.6 millilitres, between 3:45 and 3:55.

19 A. I think that is correct.

20 Q. We then know that the baby
21 was given, at some time shortly thereafter, atropine
22 and morphine.

23 A. Yes.

24 Q. We know then that the Code on
25 this baby was called at 4:20.

26 A. Right. Approximately 25 to 30

27

28

29



1

2 minutes later.

3 Q. Yes. We then know that an
4 arrest procedure was carried out. In the nurse's
5 notes on page 29 we see that CPR was carried out,
6 that is the nurse's charting of it?

7 A. Right.

8 Q. And if CPR is carried out,
9 Dr. Kauffman, I gather that the aim of that is to
10 maintain circulation?

11 A. Yes, that is the aim.

12 Q. And if we read on the bottom
13 of page 27 with respect to this arrest --

14 A. Yes.

15 Q. -- I guess it starts towards
16 the bottom that this atropine 0.2 mg. was giving
17 good response; the heart rate is 140 per minute; the
18 anaesthetist is called and at that time the child
19 displays ventricular fibrillation.

20 A. Right.

21 Q. I gather shock was given with
22 good results.

23 A. Then she had a blood pressure
24 noted of 110 momentarily at least.

25 Q. Yes.

A. And then she went back into the
26 fib.



1

2

3

4

Q. That would indicate some circulation at least that some heartbeat had been obtained by the resuscitation effort?

5

A. At least momentarily.

6

Q. And we know that they stopped some 36 minutes, that is at 4:56 in the morning.

7

A. That is correct.

8

Q. And we know that in the middle of that resuscitation, not really in the middle but at 4:30, ten minutes into the resuscitation attempts the serum level was taken and that produced the 72 nanograms per ml. We also know that a further sample was taken at 0600 hours, and I believe that that is 6.

14

A. That is approximately an hour after the Code was discontinued.

16

Q. No, sir. Oh yes, an hour after the Code.

18

A. Is that correct?

19

Q. Yes, an hour and four minutes after the code.

20

A. Okay.

21

Q. And we know then --

22

A. I'm sorry, I don't know where that second sample was obtained from, I have forgotten.

24

25



1

2 Q. I don't know either.

3

A. Do we know?

4

MR. BROWN: I believe that is the

5

sample taken from the puncture of the heart.

6

MS. SYMES: Q. I will accept

7

Mr. Brown's --

8

A. I will accept that if nobody
corrects it.

9

Q. The sample from the puncture of
the heart. Now, in the calculations of the minimum
dose which you did for us on the first day, I gather
that you said in your answers to Mr. Scott yesterday
that the answers are only as good as the assumptions
which you made.

10

A. I think that is true.

11

Q. And I believe that you said
yesterday, on the first day, that the information
that you were using is that the dose is equal to the
concentration times the central volume of distribution
times the body weight.

12

A. I believe so. The volume of
distribution in terms of litres per kilogram.

13

Q. In terms of litres per kilogram?

14

A. Right.

15

Q. And in this particular case

16

17



1

2 we didn't really have to assume because we can read
3 from the chart that the body weight was 5.37 kilograms.

4 A. Right.

5 Q. And what we were interested in
6 was what dose had to be administered in order to get
7 a concentration of .070, is that correct?

8 A. It depends what unit you were
9 using.

10 Q. What unit should that be, it
11 was 70 nanograms per ml.

12 A. I think it was reported as
13 70 nanograms per ml., that would be 70 micrograms
14 per litre, you might put it into litres so that
15 everything is the same.

16 Q. So that is micrograms?

17 A. Per litre, and then take the
18 decimal point off it is 70, it is not .07, it is
19 70.

20 Q. The volume of centre of
21 distribution should then be in litres per kilogram?

22 A. Yes.

23 Q. Now, when you plugged these
24 numbers into the equation you assumed then that the
25 centre volume of distribution was 1.3, and I believe
that when you did that calculation putting it in, if



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Kauffman
cr.ex. (Symes)

6347

1

2 the volume of central distribution is 1.3, then the
3 dose turned out to be 0.5 mg.?

4 A. As I recall that is correct.

5

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3
I/EMT/ak

Q. And that was equal to 10
pediatric vials.

A. Let's see, there is .05 milligrams per millilitre.

Q. And one pediatric --

A. And one vial.

Q. So that would be 10?

A. That would be 10, right.

Q. Or one adult vial?

A. It would be less than one adult vial, wouldn't it? Aren't there 2 millilitres in one adult vial when the concentration is .25, so it would be one adult vial, you are correct.

Q. Now, when you initially gave your evidence on the first day you said that for the central volume of distribution --

MR. HUNT: What is reference, please?

MS. SYMES: At page 5521, Mr. Hunt.

Q. That you could have equally used .5, .6.

A. I am sorry, what page?

Q. 5521.

A. Okay.

Q. You said you could have equally used .5, .6, .81, et cetera.

25



Kauffman, cr.ex.
(Symes)

1

I.2

A. Yes.

2

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Q. And in fact the range then that you have posited is somewhere - that you have posited for volume of central distribution is somewhere between .5 and .13.

A. Yes. I think actually the studies that I used to give me some basis for selecting the number were .6 something to 1.3.

Q. Let's take then this mathematical exercise that you did and try and calculate the dose over the range of volume of central distribution to see what we get.

A. Okay.

Q. And if we take the volume of central distribution, let's take the minimum to be 0.6, and if we plug those into the equation and if I can - if my calculator is able to --

A. I can save you some time. You can just divide it by half.

Q. All right. So I believe that the dose is equal to --

A. .2 something.

Q. I got .23 when I did it.

A. Well, it should be --

Q. It should be higher?



1.3

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2
3 A. It should be - well, .6 is
4 about half of .3 so this would be how you would come
5 out, that is correct.

6 Q. Now if we try and put that
7 since .23 of a milligram doesn't help me very much
8 in understanding how much to give, that would be
9 6 pediatric vials. No, I'm sorry, that would be
10 4.6 pediatric vials.

11 A. Yes.

12 Q. Or it would be 0.46 of an
13 adult vial? Would you agree?

14 A. I think that is correct, yes.

15 Q. Let's try the next one. If we
16 take the volume of central distribution to be 0.8,
17 moving up to the range.

18 A. Right.

19 Q. And if again my calculator is
20 correct I believe that this dose turns out to be 0.3.
21 I think I have done it correctly. I simply put in
22 the numbers --

23 A. I will accept that your
24 arithmetic is correct.

25 Q. That my batteries still work?

26 A. Yes.

27 Q. And that we then have - that is



1

2

I.4

equal to 6 pediatric vials or 0.6 adult vials.

3

A. Okay.

4

5

6

7

8

9

Q. Let's do the last one just so

that we have a range. If the volume of central distribution is 1, 1 litre per kilogram, then I believe the dose turns out to be .38. And if the dose is .38 then I believe that the pediatric vials needed are 7.6.

A. I think it is superfluous to use so many decimal points, but that is okay.

10 Q. Well, I am more interested in
11 the adult ones.

12 A. Yes.

13 Q. 0.6 of an adult vial.

14 A. Okay. Almost an adult vial.

15 Q. Well, three-quarters of an
16 adult vial.

17 A. Three-quarters.

18 THE COMMISSIONER: 0.76. All right.

19 MS. SYMES: Q. You would agree with
20 me then, that if we change the assumption of the
volume of central distribution --

21 MR. HUNT: Sorry, that is 0.76.

22 THE COMMISSIONER: Yes.

23 MR. HUNT: You said 0.6.

24 MS. SYMES: 0.76. I'm sorry.

25



1

2

1.5

THE WITNESS: It is 0.76 of an adult
3 vial.

4

5

MS. SYMES: Q. 0.76 which is
three-quarters of an adult vial.

6

A. Right.

7

Q. And you would agree with me
then, Dr. Kauffman, that the numbers that I have
given - let's just take the adult vial, that in order
9 to produce a concentration of 70 nanograms per ml in
10 this baby that weighs 5.37 kilograms the range is
11 from .46 of an adult vial to one adult vial.

12

13

A. From somewhere a half to one
vial.

14

Q. Yes, okay.

15

16

17

18

A. And as I said I think the
other day I was asked why I picked that particular
number and I said I had two studies that gave me that
number, and one study that gave me the .63 so I
decided to go with the majority.

19

Q. Okay.

20

21

A. But I have no quarrel with
this exercise.

22

23

24

Q. But we have literature reviews
then that put it in the entire spectrum that I have
written on the blackboard.

25



1.6

1 A. That is correct.

2
3 Q. And Dr. Hastreiter I gather in
4 a recent paper has calculated it as 0.62.

5 A. Yes. In fact I think that is
6 his data that I was referring to for the .6.

7 Q. For the bottom one?

8 A. Yes.

9 Q. And if we look at Exhibit No.
10 268 which is an Hastreiter article - I believe that
11 has been put before you - on page 26 of that --

12 A. Can you tell me which article?
13 Q. It is the article called
14 "Digoxin Pharmacokinetics in Premature Infants".

15 A. Right.

16 Q. In Pediatric Pharmacology, 1982.

17 A. Right.

18 Q. Would you turn to page 26 of
19 that, and in that paper at the bottom, Dr. Hastreiter
20 is referring to the volume of central compartment.
21 Is that the same thing the volume of central compartment
22 or the volume of central distribution?

23 A. I think that he - I can't
24 speak for him. I would read his paper as meaning that,
25 yes.

Q. And he got in this one 0.62



Kauffman, cr.ex.
(Symes)

I-2
EMT/cr

1
2 Q. "The volume of the central
3 compartment for the premature patients
4 is significantly lower than the values
5 reported for full term neonates and
6 older infants".

7 A. Where are you reading?

8 Q. Just continuing the sentence.

9 A. I am sorry, we must be on
a different page.

10 THE COMMISSIONER: I think on 28 we
11 find it.

12 MS. SYMES: Q. The sentence continues
on page 28.

13 A. Well, I am on page 26.

14 Q. Yes, the sentence begins on
15 page 26 and ends on page 28.

16 A. "The volume of the central
17 compartment for the premature infants
18 is significantly lower than the values
19 reported for full term neonates and
20 older infants".

21 That is what you are referring to?

22 Q. Yes.

23 A. Okay. I am with you now.

24 Q. And is it logical that the

25



1

2 central volume of distribution would increase as
3 children grow?

4 A. You might extrapolate that
5 from this.

6 Q. From that ambiguous sentence?

7 A. From this information, but I
8 don't think we know that for sure. All he is saying
9 is that a very small group of prematures he observed,
10 the way he did the study, he observed a different
11 calculated central compartment distribution, and he
12 is saying that it seems to be smaller than in the
13 older age groups.

14 Now whether you could conclude from
15 that with statistical validity that there is a change,
16 a rate of change as the baby matures I don't know.
17 You might. It might be a reasonable deduction. I
18 don't think you can do it with a great deal of
19 certainty yet with this amount of material. We do
20 know there is a difference.

21 Q. We do know. And we would
22 then in this exercise that I have just gone through
23 have a possibility of delivering 70 nanograms per
24 mil of digoxin in Justin Cook by .46 of an adult
25 ampule and .6 or three-quarters of an adult ampule
or a full one?



1

2-3

A. Well ---

3

4

Q. That is leaving all of the
rest of your assumptions that you made the same.

5

6

7

8

9

A. I would agree with you in
general. My discomforture is that the .6 volume
distribution is for premature infants in infancy or
in the newborn period apparently according to Dr.
Hastreiter's data, and I don't remember whether Justin
Cook was a premature infant.

10

11

12

Q. I don't know that Justin Cook
was a premature infant and quite frankly he was
almost three months of age.

13

A. And if the data ---

14

Q. Three months and 29 ---

15

16

17

A. So it may not be appropriate
to use the central volume distribution central
compartment for the premature group to apply to
assumptions on Justin Cook.

18

19

20

21

22

I didn't have this paper when I did
my calculations a year ago because it just came out
now, but I am thinking now it may not be appropriate
to use that lower number because the patients from
which it is derived may not be comparable to this
specific case.

23

24

25

Q. Well just as we might take



Kauffman, cr.ex.
(Symes)

1

2 off the bottom number on this range we might
3 similarly take off the top?

4 A. Yes.. I would agree with you.

2-4

5 Q. Now when ---

6 A. I think we can fairly say
7 probably somewhere between .8 and 1.3, and if you
want to agree on 1 that is an easy round number.

8 Q. Or we could agree as between
9 .6 and three-quarters of an adult vial.

10 A. I think - you are right, yes.

11 Q. So on page 5512 of Volume 70
12 you were asked by Miss Cronk as to whether or not the
13 volume of Inderal which was .6 of a millilitre that
14 was administered at 3:45 and 3:55, that is a total
15 of .6 in total, if that that had been digoxin instead
16 of propanolol or Inderal could that have produced the
concentration of 70 nanograms per mil.

17 I guess it is fair to say that the
18 exercise we have just gone through was that that
19 number is within the realm of possibilities?

20 A. Well, is it?

21 Q. Sir, .6 of an adult vial is
if a volume of central distribution is .8.

22 A. Yes. I think that these
23 assumptions that you arrived, I would agree with you.

24

25



1

2 I went on to say I didn't think these assumptions
2-5 would fit the situation but if you go with these
3 assumptions, I would agree with you.
4

5 Q. Just so that I understand
6 it clearly, the .6 if it had been propanolol or
7 Inderal, just on this one mathematical model, could
8 have produced a concentration of 70 nanograms per
9 mil?

10 A. Yes.

11 Q. Using all the same assumptions
12 that you did?

13 A. If I accept the volume
14 distribution of .8.

15 Q. And now I am going to move
16 on to the next thing which is the time, and would
17 this be an appropriate time?

18 THE COMMISSIONER: I have lost track,
19 what are we talking about at 5512? Are we now
20 talking about a minimum dose?

21 THE WITNESS: Yes.

22 THE COMMISSIONER: Or are we talking
23 about ---

24 THE WITNESS: No, this was the minimum.
25 This was my minimum dose calculation.

26 MS. SYMES: Mr. Commissioner, what has
27

28



1

2 happened is that the minimum ---

3 THE COMMISSIONER: I understand. I
4 understand.

5 MS. SYMES: - that the minimum has
6 gone down.

7 THE COMMISSIONER: Well, the minimum
8 could have been - what you are trying to establish
9 is that the minimum dose accepting all of those
10 assumptions, resulted in a minimum dose. It could
11 have been propanolol; that could have been a mistake.

12 Is that right?

13 MS. SYMES: Yes, and theoretically it
14 could have gone down as low as .46 of an adult vial,
15 but if we take off the bottom - we take off the top
16 from the range then somewhere between .6 or .8 -
17 .6 or .76 of an adult dose ---

18 THE COMMISSIONER: Dr. Kauffman
19 said at 5512 I think it is somewhat unlikely.

20 MS. SYMES: Sir, I think in his
21 mathematical calculation it was totally unlikely
22 because it was completely out of the range.

23 Q. Isn't that so, sir?

24 A. No, I don't think that was
25 the intent of my comment at that point. I thought
it was unlikely for other reasons.



1

2

Q. Well, specifically you were
being asked at that point to calculate minimum dose?

3

A. That is right.

4

Q. And the minimum dose that
you gave in evidence was larger than that .6 of a
vial?

5

A. That is right.

6

Q. So I mean it was more than
unlikely; it just didn't fit your mathematical model
at all?

7

A. But that was not my reason
for saying it was unlikely.

8

THE COMMISSIONER: Mainly because of
the tissue concentration.

9

THE WITNESS: Right.

10

THE COMMISSIONER: Then we will deal
with that after the break. We will take 20 minutes
now.

11

---Short recess.

12

13

14

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16

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18



J/BM/ak

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---Upon resuming.

3

THE COMMISSIONER: Yes, Miss Symes.

4

5

MS. SYMES: I'm wondering if I could have the exhibit which is the vials, Exhibit 225.

6

THE COMMISSIONER: Yes.

7

8

9

10

MS. SYMES: Q. Dr. Kauffman, we have had these vials of different medications put in as exhibits before us and this little brown bottle I gather is the Inderal that would have been available on 4A/4B during the epidemic period.

11

12

13

14

15

I gather then when Inderal is being dispensed that the standard practice would be to draw up the entire content of the vial and then to inject whatever you need from that; if you need .1 or .8, is that the standard thing?

16

A. I don't know.

17

Q. Well, what would you do?

18

19

20

21

22

23

24

25

A. Usually if I am going to discard the vial I would draw up the amount I was going to give and then discard the rest of the vial.

Q. If you didn't know how much you were going to give, that is, it was for a potential emergency situation, you didn't know if you needed .2 or .8.

A. And I knew the patient I was



J2

1

2

going to give it to?

3

Q. Yes.

4

A. I would probably draw up the dose appropriate for that patient.

5

Q. Would you, by the way, ever draw up from the ampule into a syringe and leave it at the end of a bed for some 10 hours?

6

A. I don't know if I would do that or not. I usually am not in a position of having to make that decision.

7

Q. Now, we know that the digoxin is called Lanoxin in our example here, that is its trade name, is that right?

8

A. That is Burroughs-Wellcome's trade name I think.

9

Q. Just going back to the Interal. If the doctor were to have drawn up, or someone to have drawn up for the doctor the entire vial and then he wished to give .5 of it, I gather he would then mentally give half of the dose.

10

A. You mean if somebody had drawn up the entire 1 millilitre?

11

Q. Yes.

12

A. And they wanted to give half of it?

13



Kauffman, cr.ex.
(Symes)

J3

1

2

Q. Yes.

3

A. Half of it would be .5 milli-
4 litres.

5

Q. But the other way is .5 is
6 half of the vial.

7

A. .5 is half of this vial.

8

Q. And it would also be half of
9 what was in the syringe?

10

A. If they left 1 cc in the syring
11 and then injected half of that with 1 cc in the syringe,
12 there should be .5 cc's left in the syringe after the
13 injection. Is that what you are getting at?

14

Q. I'm just trying to go through a
15 very simple exercise and, that is, if the person
16 administering the drug thinks that he wants to give
17 .5 of a milligram of Inderal or .5 I guess of an ml
18 of Interal.

19

A. Yes. You have to keep volumes
20 and milligrams separate.

21

Q. All right. I would then know
22 I should give half of what's in the syringe.

23

A. If he had a millilitre in the
24 syringe and he wanted to give .5 he should give half
25 of what is in the syringe.

Q. Okay. Now, if we look at



J4

1

2

3

lanoxin, which is what digoxin is, this is what I
gather from evidence the adult size?

4

A. Yes.

5

6

Q. Okay. And if all that were
drawn up into a syringe.

7

A. Yes.

8

Q. And one half of it were given,
that is, one half of what was in the syringe was given.

9

A. Yes.

10

11

Q. In that particular case it would
be one half of 2 mls, which is 1 ml.

12

A. This is a 2 millilitre vial.

13

Q. It says so, doesn't it?

14

A. Yes.

15

Q. Yes.

16

A. And so if you had all of that
2 millilitres in the syringe and you gave half of it
you would give 1 millilitre.

17

18

Q. So, if the doctor thought - I
am positing an error to you - that in fact what was
in the syringe was 1 ml of Inderal but in fact was
2 mls of digoxin and gave one half of this syringe,
that would in fact produce 1 ml of digoxin?

19

20

21

A. No, no. 1 ml, yes.

22

23

Q. Yes.

24

25



1

2

J5 A. If the individual didn't look
3 at the syringe.

4

Q. Yes.

5

A. And didn't look to see how
6 much they had to begin with and they had 2 millilitres
7 in the syringe and they gave half of it they would
8 give 1 millilitre.

9

Q. That's right. So, in other
10 words, if one does a calculation - I mean, these
11 bottles I guess look different but if you were in a
real rush.

12

A. They look quite different to

13 me.

14

Q. Well, one of them is brown.

15

A. And they are different sizes
16 too.

17

Q. Different sizes.

18

A. And the lettering and the
label is different.

19

Q. But if this vial was not
available to the doctor when giving, he would
obviously not know what was in the drug, what was
in the syringe, what drug was in the syringe.

20

A. That's correct. I assume that
this is a clear solution, I can't tell through the

21

22

23

24

25



Kauffman, cr.ex.
(Symes)

J6

1

2

coloured glass.

3

Q. It is our information that it
is clear.

5

A. Is that correct?

6

7

Q. Yes, they are both clear
solutions.

8

9

10

A. So, if you had a clear solution
in the syringe and the syringe was unlabelled you
would have no idea whether it was water or anything
else.

11

12

13

Q. And if the doctor didn't have
the vial to refer to when he was actually injecting
the medication he wouldn't have a check.

14

15

16

A. Yes. I would hope he would
want to make sure that he knew what was in it though
before he injected it.

17

18

19

20

21

Q. Right. Now, in terms of
the timing of the dose of digoxin, we know that the
sample was drawn at 4:30 in the morning and that
death was at 4:56. The sample produced 72 nanograms
per ml and the fresh tissue from the heart muscle was
eleven seventy-seven nanograms per gram.

22

23

24

On pages 5534 and 5535 you said that
it could have been administered, your best estimate
was that it could have been administered 1, 2 to 3

25



J7

1

2

hours before death.

3

4

A. I remember we had some
discussion as to what I meant by that, so, I want
to see ---

6

7

MS. CRONK: Could I have the page,
please..

8

MS. SYMES: 5534, 5535.

9

MS. CRONK: Thank you.

10

11

MS. SYMES: Q. That it was adminis-
tered some time between 1 to 2, 1 to 3 hours prior to
death.

12

MS. CRONK: I'm sorry, Dr. Kauffman.

13

THE WITNESS: Go ahead.

14

15

MS. CRONK: You will recall, sir,
that there have been two discussions about timing.
Miss Symes at the moment is referring to the exchange
in chief between Dr. Kauffman and myself and during
that exchange his evidence was that it was 1 to 3
hours prior to the time at which the ante mortem sample
was taken which/ and it was not the time the child was
pronounced dead. Subsequently there was a different
exchange between Mr. Strathy and Dr. Kauffman yester-
day morning which had to do with three different time
frames. So, I think to be fair to Miss Symes.

16

17

18

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MS. SYMES: I am exactly -- that is



J8

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my whole point of going through here is starting at this thing and trying to narrow you down as to when you would place the time of the administration.

5

6

As Mr. Brown referred to the window of administration in another case ---

7

MR. HUNT: Could I ask you a question?

8

MS. SYMES: Yes.

9

10

11

12

13

MR. HUNT: Are we finished with the calculations on the board, because I think the Doctor had something he wanted to say after recess about the calculations that you went through before the recess and if we are leaving that area this is a good time to do it.

14

15

MS. SYMES: Well, you will have your chance to do reply.

16

17

THE COMMISSIONER: No, but the calculations disappear off the board, it will be off the board.

18

MS. SYMES: Oh, I see.

19

20

21

22

23

24

THE WITNESS: My problem is I think I may have inadvertently agreed, not seeing an inherent error and I want to make sure that we aren't doing something, either I originally made an error or we made an error when we went through this just now. I'm not certain I know where it is but I would like to

25



J9

1

2

go through it again and see if there is an error.

3

MS. SYMES: Q. A calculation error?

4

A. Yes.

5

Q. Do you want to mark down my
numbers?

6

A. Well, I think I understand.

7

8

9

10

With your permission, I would like to finish it now
and see whether or not I agreed to an inherent error
in our assumptions here, or I can write this down and
we can come back to it later.

11

12

THE COMMISSIONER: Whatever it is you
want to do.

13

14

THE WITNESS: It would be easier for
me to do it now.

15

THE COMMISSIONER: All right.

16

17

18

THE WITNESS: Assuming the .6 milli-
litres being administered and assuming it was adult
digoxin, that would give an amount of .15 milligrams,
I believe, isn't that correct?

19

20

MS. SYMES: Q. Yes. I have just
done that last with you.

21

A. Yes.

22

23

Q. Dr. Kauffman, with respect to
the vials.

24

25

A. So, that is, may I write on



Kauffman, cr.ex.
(Symes)

1

2

J10 your sheet here?

3

Q. Of course.

4

5

A. That would give us a total dose under those assumptions of 150 micrograms, is that correct?

6

Q. Well, now wait a second, .6?

7

A. Yes, .6 millilitres.

8

Q. Yes.

9

A. Of adult digoxin.

10

Q. Yes.

11

A. Which is .25 milligrams per millilitre.

12

Q. Yes.

13

A. Right, equals .15 milligrams of digoxin.

14

Q. Right.

15

A. Is that correct? I think it is.

16

17

18

19

20

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25

Now, that equals - I am just changing the units now to make it easier to go ahead - that equals 150 micrograms of digoxin. I want to go through it slowly and label everything so I make sure we aren't making an error. That is a dose where postulating would have been administered in .6 millilitres over a 5 minute period.

Q. Yes. Sir, is that of digoxin?

✓ 80-
63-3



1

A. Of digoxin.

2

Q. Yes. .6 of millilitres, yes.

3

A. You see, .6 millilitres in the
adult preparation contains .25 milligrams per milli-
litre.

4

Q. Yes.

5

A. So, .6 millilitres would
contain this amount of digoxin.

6

Q. Yes.

7

A. Right. This .15 milligrams
equals 150 micrograms.

8

Q. Yes.

9

A. I have just changed the units,
done nothing else to it.

10

Q. Yes.

11

A. This goes into some volume to
produce the concentration.

12

Q. Yes.

13

A. Then we assume the .8 that
we were talking about here. The baby weighed 5.37
kilograms and the volume distribution was .8 litres
per kilogram. So, we come out with an absolute
volume that we are talking about to distribute this
dose into a 4.3 litres.

14

Q. Yes.

15

16

17



Kauffman, cr.ex.
(Symes)

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J12 A. And if you divide .6 - I mean, if you divide 4.3 litres into 150 micrograms you come out with 34 micrograms per litre rather than 70.

Q. Yes.

A. So, I thought we had an error but I didn't know where it was. So, giving this dose, what I am saying is, giving this dose of .6, even assuming this volume, the lower volume, would not be predicted to produce a concentration in the neighbourhood that we were talking about. Now, have I made an error?

Q. The one thing is, sir, that this was the proportion of adult vial or pediatric vial. I completely understand and that is why I had you go through the exercise with the 1 ml and the 2 ml vials. This calculation that we had done was .6 of an adult vial. .6 of an adult vial is 1.2 mls.

A. That's right, it would be twice the volume.

Q. Exactly.

A. So, the individual would have to not only select the wrong drug but give the wrong volume.

Q. Or conversely someone else might have selected the wrong drug.



1

2

J13 A. I just said an individual,

3

whatever.

4

Q. Let's make it two separate -
5 I quite agree with you.

6

A. I didn't realize at the time
7 you were postulating two sequential errors.

8

Q. Yes.

9

A. I was just looking at the
exchange in drugs.

10

Q. I want to make this very clear.
11 These are percentages or proportions of vials.

12

A. I understand that but I thought
13 you were going volume per volume, I didn't realize
14 you were multiplying times 2 of the volume.

15

Q. You have to because they are
16 in different vials.

17

A. Yes. You see, when I did my
calculations I assumed they made an error volume per
18 volume not that they made two errors.

19

Q. Yes, but if one person had made
20 the error and put the wrong drug, drawn up the wrong
21 drug into the syringe, that is, drawn up an adult vial
22 of digoxin for one vial of Inderal and then had
23 given, as I said in my example to you before, half
24 of the adult vial, half of the amount in the syringe

25



J14

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thinking that they were giving half of a vial of Inderal, that definitely is a second mistake but it would produce in this particular example .6 of an adult vial would produce 1.2 millilitres of digoxin.

A. Given that scenario, yes.

Now I see where we were different, thank you.

Q. I mean, the example is correct, the calculations are correct and, you are right, you have to do the second step which I did with the vial.

A. Yes.

Q. Yes.

A. If you assume the volume error as well as the switch error then we come out the same place.

Q. And the error is that the doctor would look at the syringe and say I want to give, for example, half of it and the reason that he might say that is because I want to give .5 of an ml. If he gives half of an adult, that is, if that is what is in the syringe, it produces - well, let's use .6 - it produces 1.2 mls.

THE COMMISSIONER: Yes, Miss Cronk.

MS. CRONK: I'm sorry again to interrupt my friend. I didn't stand and interrupt when Miss Symes put the vials to Dr. Kauffman



Kauffman, cr.ex.
(Symes)

1

2

5 because I thought she was then putting a hypothetical.
3 She suggested at that time, according to my notes, that
4 there was a vial attached to the syringe of the drug
5 that was attached to the end of the bed. We of course
6 have heard in evidence that Dr. Kantak was recorded
7 to have administered the drug, testified at the
8 preliminary hearing that attached to the syringe was
9 an empty vial of Inderal.

10 Now, in fairness to the Doctor, I
11 simply suggest that obviously what I thought was a
12 hypothetical was not a hypothetical and, if that's the
13 case, then he should be told what Dr. Kantak's
14 evidence was and being invited to express an opinion.

15 MS. SYMES: Well, Miss Cronk, you
16 also note that there may be other evidence to
17 question that.

18 MS. CRONK: Well, at the moment I
19 don't, Miss Symes. I mean, if there was other evidence
20 at the preliminary hearing I would like to know about
21 it.

22 MS. SYMES: There is nothing I know
23 of in the preliminary hearing and I am putting it to
24 the Doctor in the hypothetical because I am sure that
25 we are going to have to hear a lot more direct evidence
with respect to the events surrounding Justin Cook



J16

1

2

before we can come to any conclusions.

3

THE WITNESS: My answer is hypothetical.

4

MS. SYMES: Q. Your answer is
hypothetical.

5

6

7

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9

10

11

Now, let's go back to the timing then
with respect to the drugs. I quite accept what
Miss Cronk has said and, that is, that there were
a number of calculations that you had done with
respect to the time and all I would like to do is
try and sort out what your best estimate with respect
to the time is.

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DM.jc
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Q. What we know then, the baby got into trouble at 0345; we know that at 0420 we have an arrest; we know that at 0430 that we have a sample taken, and that is the sample that produced 72.

A. CPR was started at 4:20, roughly.

Q. Starting here at 4:20 according to the nurse's notes on page 29, and we have 456 code stopped. Theoretical or actual death I guess at 4:56?

A. Yes. I suspect death was occurring during that entire 1-1/2 hours.

Q. Now, one of the problems is how much circulation and profusion they were able to effectively produce with the CPR, that is a concern, isn't it, in any arrest?

A. You hope you produce enough to maintain the patient's oxygenation until you can establish a normal heart rate.

Q. And if CPR is continued would it then be distributing blood throughout the body?

A. To some degree.

Q. And if digoxin is in the blood digoxin would also be being distributed to the body?

A. It could be.

Q. Now, if we look at Exhibit 217-1



K.2

1

2 I think Mr. Elliot has put it in front of you, it is
3 a distribution chart that was put in evidence by
4 Dr. Spielberg.

5 THE COMMISSIONER: This is what number?

6 MS. SYMES: 217-1.

7 THE COMMISSIONER: An exhibit?

8 MS. SYMES: 217-1.

9 THE COMMISSIONER: Oh, yes, all right.

10 MS. SYMES: Q. Do you have it in
front of you?

11 A. Yes, I have it, thank you.

12 Q. That was presented to us as
13 a pictorial representation of the distribution and
14 elimination phase of digoxin over time, plotted on
a logarithmic basis.

15 A. From serum?

16 Q. From serum.

17 A. I assume this was hand drawn
18 by Dr. Spielberg?

19 Q. Maybe he did it with a ruler.

20 A. I don't know, I was just asking
21 did it represent real data, or was it from a publication,
22 or did he just give this to you as an example of an
23 illustration of what he was talking about?

24 Q. I think it was his illustration.

25



K.3

1

2

A. Of what he was saying at the
time.

3

4

Q. Of what he was saying at the
time. The question is, he has postulated that in the
alpha phase the half life for distribution is 30
minutes, and I think you have agreed that that is
reasonable.

5

6

A. I have agreed that the alpha
half life in serum is 30 to 60 minutes.

7

8

Q. And that the volume of
distribution in this I think he has postulated as
from .6 to 1.

9

10

A. Which is essentially what I
talked about.

11

12

Q. And then he has talked about
the beta phase which is the elimination from serum,
and he has postulated that to be from 20 to 80 hours.

13

14

A. Yes.

15

16

Q. And I believe he told us it
would be about 5 half lives to distribute.

17

18

A. You would expect the serum to
have reached equilibrium with the rest of the body in
5 of these alpha half lives.

19

20

Q. Now that is using a half life
as 30 minutes, that would give 2-1/2 hours, isn't that
correct?

21

22

23

24

25



K.4

1

2 A. Yes. Yes, is that right,

3

5 times 3 is 150 minutes, is that 2-1/2 Hours?

4

Q. Yes.

5

A. Okay.

6

Q. If digoxin were given either
in error or in any way administered around 3:30 to
3:45; if digoxin were administered at the top number
and a sample were taken at 4:30, that would have had
then 45 minutes in which to distribute, to an hour?

10

A. There would have been,

11

assuming that there was reasonable circulation --

12

Q. Yes.

13

A. There would have been about
45 minutes for the digoxin to be equilibrating outside
the serum.

15

Q. And that would be within 1 to
1-1/2 half lives?

17

A. That is correct.

18

Q. And during that period of 1 to
1-1/2 lives, I understand that whatever amount of
digoxin that there was in the serum one-half of it is
gone after 1 half life?

21

A. You have to remember that
these are hybrid constants, so that the alpha half
life represents one process that is removing digoxin

24

25



K.5

1

2 from the serum. The beta, which we call elimination,
3 is a second process that is removing it, and so these
4 are going on simultaneously, they don't operate
5 independently. So you can say it this way and be
6 correct; that within one alpha half life half of the
7 digoxin that is going to leave the serum due to
8 distribution would be gone, but it won't be half of
9 what was there because the beta process, or the
10 elimination process is accounting for part of it,
11 it is a hybrid function, do you understand what I am
saying?

12 Q. Yes.

13 A. Okay.

14 Q. I understand the two things
15 operate simultaneously. Of course the alpha with a
16 30-minute period and the beta with a 20 to 80 hour
17 period, the alpha is going to predominate, isn't it?

18 A. The rate of decline tends to
19 be controlled by the - in elimination by the more
20 rapid of the two processes, the constants during that
21 period.

22 Q. Yes, because one of them is a
23 much sharper curve?

24 A. That is not why, but the curve
25 describes it.



K.6

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Q. The curve describes that the
sloped end, that is the rate of change, is much faster?

A. That is right.

Q. In the alpha curve?

A. That is right, the concentration
of serum is much faster in the alpha phase than the
beta phase, that is right.

Q. So it wouldn't be far wrong
in the first half life then to say that the alpha is
going to predominate?

A. I think it defines the
dominant slope of the curve, yes.

Q. Fine.

A. Actually what you actually
see are not two sharp curves as you have drawn them,
you see a curve linear, a curve linear graph.

Q. It is exponential, isn't it?

A. Well, he has drawn exponential
but it isn't a sharp break like that, it is a curve
linear's picture when the points reflect usually.

Q. I only want to talk of course
about the very steepest part of the alpha curve at
this point, and that is during the first or 1-1/2
half lives when I gather digoxin is coming out of the
serum and into the tissues?



K.7

1

2 A. Well, it is coming out of the
3 serum and going some place.

4 Q. During that 1-1/2 half lives,
5 I gather that the digoxin would commence binding to
6 the heart?

7 A. Some of it would.

8 Q. You say that the digoxin comes
9 out of the serum and goes into tissues; would the
going into tissues depend upon which tissues?

10 A. Well, I think it is fair to
11 say it goes into tissues. The rate at which it goes
12 into various areas of the body apparently is quite
13 variable.

14 Q. Okay.

15 A. You have to think in rates
16 while we are talking about this.

17 Q. All of this I gather we can
18 quantify, we can describe qualitatively what we think
happens, is that right?

19 A. I think we can talk qualitatively,
20 yes.

21 Q. So that when the blood is,
22 half of the digoxin is leaving the serum, is it
23 reasonable to say that the tissues that it goes into
24 at first are most likely those that are profused most
greatly with blood?

25



K. 8

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A. During the early distributive phase the drug tends to get to the high blood flow organs first. There are many other factors that influence the rate, but blood flow during that period of time is an important factor.

Q. And the heart is one of the tissues, or one of the organs that has a large, relatively a large blood flow through it?

A. Yes, normally it does, yes.

Q. What are the other factors that depend upon which organ or which tissues digoxin would adhere to first?

A. It depends on the make-up of the tissues in terms of their protein, fat, water content. Whether or not there are specific binding sites, or the affinity of non-specific binding sites for the drug; and the drug solubility and various components of that tissue in the brain, the blood brain barrier seems to make it very difficult for digoxin to get into the main parts of the brain very rapidly.

Q. So blood doesn't go through to the brain; we have one thing was the profusion over the tissue or the organ. The other thing was the number of receptors, are they specific or non-specific in tissue?



K.9

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A. Well, I hate to talk about
receptors.

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A. Well, I hate to talk about

Q. Would you call them binding
sites?

A. The affinity of various binding
sites for the drug.

Q. And does the heart have a
high affinity for binding?

A. It has, it seems to be at
equilibrium, it is one of the organs where higher
concentrations are seen, yes.

Q. Do we know that the digoxin
when it leaves the serum and goes into the tissues,
that as time continues the digoxin may leave the
initial tissue that it is attached to and move to
another tissue?

A. Yes. I think that there is,
during this period of time there is probably
re-equilibration occurring as total body equilibrium
ensues. Because initially you would anticipate seeing
higher concentrations of the high blood flow organs,
and then as you approach equilibration you could have
some digoxin coming out of those tissues and being
carried off to another spot as everything equals out
to what it is eventually going to be a few hours later.



K.10

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Q. In the initial period, in the initial first alpha half life, and say the second alpha half life --

5

A. I beg your pardon?

6

Q. In the first alpha half life.

7

A. Yes.

8

Q. The first 30 minutes --

9

A. Okay.

10

Q. -- or the next 30 minutes.

11

A. Okay.

12

Q. In that period of time can we agree then that the digoxin that is leaving the serum proportionately will be found higher in tissue in the heart. If we were to sort of click a picture --

13

A. Higher than what?

14

Q. Than it would be if it were taken say 2-1/2 hours later?

15

A. No, not necessarily.

16

Q. Why?

17

A. Because some of the data I

18

have seen suggests that for some reason the rate of distribution is momentarily higher, for example in the kidney, than the heart, compared to steady state concentrations. So you have to compare the ratio of what the heart concentration would be at the moment

19

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K.11

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2 in time you are postulating compared to what it would
3 be at equilibrium; and then what the concentration in
4 the reference organ would be at the same time during
5 distribution related to what it would be at equilibrium
6 and this gives you some idea, it is not a good
7 measurement, but it gives you some clue as to what the
relative weights of distribution may be.

8

9 In other words, what I am saying you
10 can't conclude from what you have just said that
11 although the heart may eventually bind a lot of digoxin
12 that its rate of uptake will necessarily be higher
relative to some other high blood flow organs. Do you
13 understand what I mean?

14

Q. I understand what you are
saying, but I didn't mean to ask that question.

15

A. That is why I asked you
relative to what?

17

Q. I didn't mean to ask that
question as to whether or not the relative uptake of
heart compared to kidney was higher. I am asking a
simpler question than that.

20

A. Okay.

21

Q. And the simple question is,
if we clicked the camera after 30 minutes, that is
the first alpha phase, and took a piece of tissue from

24

25



K.12

1

2 the heart and measured the digoxin level, then waited
3 until the alpha phase, the distribution phase was
4 more or less complete, 2-1/2 hours later and clicked
5 the camera again and took a bit of tissue from the
6 heart; would the level of digoxin in the heart be
higher in the first than in the second?

7

A. I would predict it would be
higher in the second.

9

Q. That it would be higher in the
10 second?

11

A. Yes, if I understand your
12 question.

13

THE COMMISSIONER: What she is asking
I think is there a greater adherence to tissue in the
14 first or in the second, that's all?

15

THE WITNESS: That question doesn't
16 make sense.

17

THE COMMISSIONER: It is obviously
more in the second, but does it proportionally come
more in the first than in the second, that's all?

19

The first half life --

20

THE WITNESS: The first half life
21 you get half of what is eventually going - the net
22 is half of what it is eventually going to be, and in
23 the second half life you get a quarter of what it
24

25



K.13

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2 is going to be; is that your question?

3

4 Q. Well yes, and further on is
5 that during the second, third and fourth alpha half
6 lives some digoxin may leave the heart and move to
7 other tissues, or other organs?

8

A. I don't know that is the case.
9 If you can show me data that that is the case I will
10 accept it, but I don't know that's the case.

11

12

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/EMT/ak

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But I don't know that that is the case.

3

Q. Do you know that after --

4

A. What I was speaking about as

5

reshuffling is that usually high blood flow organs
with slow binding affinities will initially have very
high concentrations because of the blood flow and
solubility, but then the higher affinity organs will
eventually take up more and the concentration in those
high blood flow low affinity organs will decrease
as later on in this distributive period.

11

12

I don't think a heart is a low
affinity organ. I think it is a high affinity organ.
so what I am saying - I used kidney as an example
because it happens to be a high blood flow organ
that has a lot of digoxin in it initially after an
acute dose, and then it drops with equilibrium.

15

16

17

18

19

The heart seems to go the other
direction. It takes it up because it has a high
affinity but the rate of uptake may be a little
slower than the kidney.

20

21

22

Q. I understand what you are
saying but the digoxin that moves, for example, to
the brain has got to come from somewhere.

23

A. True.

24

Q. So it is going to come partially

25



L2

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2

from the heart?

3

A. I don't know how much of it.

4

I doubt if very much of it does. I suspect that it comes from tissues where there is less affinity for it.

7

8

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14

But we have to remember that when a molecule of digoxin goes to one spot, it doesn't stay there. I am afraid people are starting to think that we are dealing with a non-dynamic situation, that digoxin goes into the blood, it gets carried to a spot and stays there forever.

15

16

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Well, that isn't what happens. You have a dynamic situation all the time because all this binding is reversible.

Q. We understand that.

A. And it is related to concentration and relative affinities.

Q. We understand that it is constantly binding and unbinding during life.

A. Right.

Q. With respect to the distribution of digoxin from serum to tissue do you agree that we know very little about it?

A. Well, I agree --

Q. -- at this particular time?



1

2

A. I agree with that.

3

Q. In terms of rates or --

4

A. We especially know very little
about the dynamics, the quantitative dynamics of its
movement into tissue.

5

Q. And I had given you last night
a case study, a case report by Dr. Hastreiter.

6

A. Yes, and I brought it with me
this morning. I thought you might mention it.

7

Q. And with respect - well, I
hope to do that. This is a report entitled "Accidental
Digoxin Overdose in an Infant Post Mortem Tissue
Concentration" and it is found in the Journal of
Forensic Sciences, and I must confess that Mr. Brown
gave it to me. I didn't find it myself. I think they
passed it out.

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2-1

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EMT/cr

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MS. CRONK: Why do you confess that?

3

MS. SYMES: Because I am honest in
attributing good research to where it belongs.

4

5

Q. In this report - could this
report and I think everyone now has a copy of it,
Mr. Commissioner. Could it be marked as the next
exhibit?

6

7

THE COMMISSIONER: Case report - what
number are we at? 276.

8

9

---EXHIBIT NO. 276: Report entitled "Accidental
Digoxin Overdose in Infant
Post Mortem Tissue Concentration".

10

11

Q. I understand that this then
is really about one particular child, a seven week
old child who was on digoxin therapy and was given
by mistake an enormous dose of digoxin? That is
2 milligrams of digoxin IV.

12

13

THE COMMISSIONER: Before you get too
deeply into this, you realize we are having the
author of this report next week?

14

15

MS. SYMES: It is specifically with
respect to the distribution into tissue, Mr.
Commissioner.

16

17

THE COMMISSIONER: Yes. All right.

18

19

I wonder if you could let me have and
perhaps we could ask Dr. Kauffman not to listen, but

20

21

22

23

24

25



1
2-2 2 what your ultimate question is because I don't
3 know where this is all leading, the ultimate
4 question ---

5 MS. SYMES: The question is in 45
6 minutes how much digoxin might we expect to see in
7 heart tissue?

8 THE COMMISSIONER: Yes. All right.

9 MS. SYMES: Q. That was essentially
10 what the purpose of this particular paper was, wasn't
11 it? It is just one child that they are trying to
12 follow and I guess by a very unfortunate accident
13 they actually got to observe a child where they knew
14 many of the unknowns or assumptions that we have made?

15 A. This was a baby apparently that
16 was known what the dose was and pretty closely to
17 when it was administered so they had a lot of
18 information that we don't have on any of these
19 cases.

20 Q. So this one then we have a
21 few less assumptions we have to make about it?

22 A. Yes.

23 Q. A seven week old baby then is
24 obviously a young baby and I believe that the child
25 weighed - whatever a child weighs.

26 Do you remember what the child weighed?



1

2

A. I don't know that it is in
the paper.

2-3

4

MS. CRONK: 4.10.

5

THE WITNESS: Oh, here it is.

6

4.1 kilos.
7
MS. SYMES: Q. And I gather that the
child then was given 2 milligrams of digoxin IV
8
and died 45 minutes later?

9

A. That is correct.

10

11

Q. That is the basics that we need
to know about this.

12

It is not clear I gather from this
particular reading whether or not the child arrested
13
and then died; whether or not CPR was performed
14
between arrest and death. None of that is
15
particularly given?

16

A. No, it isn't.

17

Q. So we can't tell, for example,
comparing it to Justin Cook whether there was good
18
circulation for 45 minutes or slightly impaired?

19

A. No.

20

Q. Or slightly impaired
circulation for 45 minutes.

21

A. The other and confusing
thing - this infant is a close twin it looks like to

22

23

24

25



1

2 Justin Cook in terms of what happened, but in terms
3 of age and levels in tissue and so forth. There is
4 one other thing that is different, though, but this
5 baby had apparently already been digitalized.

6 Q. Exactly.

7 A. And that makes ---

8 Q. That makes quite a difference?

9 A. That creates an unknown.

10 Q. The digoxin had been prescribed
11 and the child had been in hospital for three weeks
12 following admission so we can leave out the other
13 variable that you used on another child, and that is
14 we can presume that digoxin was given for that three
15 weeks?

16 A. We hope that administration
17 is better at the hospital than at home.

18 Q. We hope. Okay. Table 1.

19 My understanding of Table 1 indicates the presence
20 of digoxin in various tissues.

21 Obviously it is post mortem and
22 obviously it is 45 minutes after the administration
23 of 2 milligrams of digoxin. Is that right?

24 A. The death was 45 minutes after.
25 I am not sure when the autopsy was actually done.
I don't recall if they say.



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Q. I don't know. I can't
remember that.

A. But assuming that there was
no significant change or redistribution prior to
autopsy I would think these are fresh levels; I
think we can accept them as being as good as anything
we have got on the other patients.

Q. On Table 1 then the controls
indicate under Tab 1 expected values or normal
values for digoxin in neonates and underneath is
in older infants and children, and the plus or minus
is the standard deviation. Is that right?

A. Is it? I don't know. When
I read this last evening I wondered about that. He
doesn't say if that is the range - I assume it is
standard deviation because this is the usual
notation, but it doesn't say.

Q. We will have to ---

THE COMMISSIONER: Who are these
controls? It is in the paper but tell me who are
they?

MS. SYMES: Q. Who do you understand
he has compared the controls to?

A. From the paper my understanding
is that these were infants who had been receiving



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2-6

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therapeutic doses of digoxin and had died for whatever
reason and in whom they had obtained fresh tissue
levels at post mortem.

3

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Q. Dr. Kauffman, they relatively
fit into the ranges which you have given us on
previous days for normal levels of digoxin in
tissue; is that correct?

9

A. They fell in that range.

10

11

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Q. Yes. The top then of Table
1 is the particular distribution of this child's
digoxin that would be within one and a half lives
if we assume a 30 minute half life; is that correct?

A. These represent concentrations
in the tissue of, following about one and a half
serum 30 minute half lives, alpha half lives.

Q. And there appears to have
been - there of course was a very large dose of
digoxin; that is 2 milligrams, but there appears
to have been a substantial amount of digoxin made
its way to the atrium ventricle of the heart?

A. Yes.

Q. Do you agree?

A. Yes.

Q. So that ---



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2-7

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2 A. One problem - the problem I
3 raised a minute ago, I don't know how much of this
4 was due to therapy. We can assume it was somewhere
5 in the neighbourhood of these control concentrations.

6 Q. This would be a neonate,
7 wouldn't this child seven weeks?

8 A. Yes, I would agree.

9 Q. So for example if the child
10 were on therapeutic digoxin we would expect in the
right atrium to have tissue concentration of 95
11 plus or minus 59?

12 A. Right.

13 Q. Is that correct?

14 A. Yes.

15 Q. But instead they got 667?

16 A. Right.

17 Q. And I could read the rest of
those exactly as is?

18 A. Yes.

19 Q. I am reading them correctly,
am I?

20 A. You read that one correctly,
21 yes. You haven't read the rest of them.

22 Q. No, no.

23 A. I am not sure we need to.

24
25



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2-8

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2 Q. But if I read the rest of them
3 the same way.

4 A. What I did was I compared
5 the same heart chamber level to the mean and standard
6 deviation of the full term neonates below it.

7 Q. And it appears that the
8 chambers vary depending on how they take up digoxin
9 in 45 minutes?

10 A. It appears that way, yes.
11 Not only the chambers but the other tissues also.

12 Q. Exactly. The only reason I
13 am concentrating on the heart is because that is what
14 we have in Cook.

15 A. Right.

16 Q. And the only thing that I want
17 to use from this - it is difficult I guess to under-
18 stand - I guess you write a paper about one
19 particular child and I guess another child might
20 be entirely different, but at least we have seen in
21 one particular child in 45 minutes a substantial
22 amount of digoxin actually got to the heart tissue?

23 A. That is correct.

24 Q. Okay.

25 A. Or it was found in the heart
tissue and we assumed that a significant portion of



Kauffman, cr.ex.
(Symes)

1

2 that that was found got there from that dose.

3 Q. There is nothing in the
4 paper whatsoever that this child was toxic before
5 he received ---

6 A. No, no.

7 Q. - before he received the
digoxin?

8 THE COMMISSIONER: Well, there would
9 have been some.

10 THE WITNESS: There would have been
11 some there.

12 MS. SYMES: Q. Oh, of course. But,
13 Dr. Kauffman, I have perceived it correctly, have I
14 not that what we would expect there would have been
approximately the 95.

15 THE COMMISSIONER: Only if it were
16 a therapeutic dose.

17 MS. SYMES: No, sir. Perhaps I
18 could try again.

19 If the child were on a therapeutic
20 dose ---

21 THE COMMISSIONER: Yes.

22 MS. SYMES: And he were being
23 maintained.

24 THE COMMISSIONER: Yes.

25



1

2 MS. SYMES: We would expect that the
3 level of digoxin in tissue would be 95.

4 THE COMMISSIONER: Oh, I see. Yes,
5 95.

6 THE WITNESS: According to this right
7 atrium.

13
2-10

8 MS. SYMES: The right atrium.

9 THE COMMISSIONER: So you subtract
10 95 from 667 and you are going to prove something
11 by that, are you?

12 THE WITNESS: Well, if you want to
13 look at extremes like we have in the other cases
14 you have to at least go 2 standard deviations above
15 and below that. So the real value - there is a
16 97 point something per cent probability that the
17 real value was between ---

18 MS. SYMES: Q. 150. Down to 30 from
19 150.

20 A. Well, it is more than 150.
21 2 standard deviations ---

22 Q. 2 standard deviations.

23 A. So it is going to be almost
24 300 down to 10 so the real value lies somewhere in
25 there.

Q. Somewhere between ---



1

2 A. I don't want you to mis-
3 represent what the possibilities are.

4 Q. Oh, no, sir, we want to be
5 absolutely precise. And similarly we could say that
6 667 might not be right; that there might be a range
7 on that as well ---

8

9 A. Well, it was right ---

10 Q. If you took a slice of
11 tissue next to it it might be slightly higher.

12

13 A. It was right in this
14 particular baby. The reason we have a standard
15 deviation in these others is we have several babies
16 and the mean from those babies.

17

18 Q. Doctor, you will agree with
19 me that if we took several slices of tissue we might
20 get a variation amongst those tissues as well.

21

A. I agree with that.

22

23 Q. So that we know - all I want
24 to extract from this particular paper is that in
25 45 minutes in one particular baby digoxin went from
the serum into heart tissue?

26

27 A. Some digoxin went from serum
28 into heart tissue I am sure.

29

30 Q. And obviously some went into

31

32

33

34

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2-12

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2 kidney, liver, fat, brain?

3

A. Yes, gut and everywhere else.

4

Q. Everywhere. Thymus and spleen
and it carries on for another two pages.

5

A. That is right.

6

Q. Going back to Cook then we
know if the digoxin administered at 3:45 - let's take
exactly the same numbers as this sample - pardon me,
as the Hastreiter paper, and we take a sample at
4:30 we have the same time frame which is 45 minutes.

10

A. You mean we give 2 millilitres
at 3:45?

12

Q. If an overdose of digoxin were
given at 3:45 - obviously any digoxin given to this
child is an overdose because he is not on digoxin.

15

A. Well, it may not be an over-
dose but it would be a ---

17

Q. More than he should have had?

18

A. - a non-authorized dose.

19

Q. If any digoxin were given to
this child at 3:45 in $1\frac{1}{2}$ alpha half lives some of it
would adhere to tissue, to heart tissue? Would you
agree?

22

A. Some of it would go to the
heart.

24

25



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Kauffman, cr.ex.
(Symes)

6406

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Q. Would you agree with me in
the remaining I think it is 26 minutes from sample
to, and I say arrest stopped, code stopped, in the
remaining 26 minutes more could go.



Kauffman, cr.ex.
(Symes)

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BB/cr

2 A. Well, I think there is a
3 possibility that digoxin, some digoxin would go to
4 the heart during that period of time shortly before
5 and following arrest and up until the time circulation
6 or the code was stopped and we assume there is no
7 circulation, not even poor circulation.

8 Q. At 4:56?

9 A. Yes.

10 Q. Yes. So that we know then
11 just in the first timing that part of the digoxin
12 would have left the serum and gone into tissue and
13 if CPR was able to maintain some circulation digoxin
14 would continue to leave the serum and go into tissue?

15 A. Say that again, I want to make
16 sure I understand you.

17 Q. From 3:45 to 4:30, which is
18 a 45 minute time?

19 A. Right, right.

20 Q. It is one and a half half
21 lives, alpha half lives. Digoxin would leave the
22 serum and go to heart tissue?

23 A. It would leave the serum.

24 Q. And go, amongst other places,
25 to the heart tissue.

26 A. It starts distributing all over.

27

28



1

2 Q. Yes. But the Hastreiter
3 article would indicate that some of it would find
4 its way to the heart?

5 A. Some of it goes to the
6 heart, that's right.

7 Q. In addition, from 4:30 to
8 4:56 if CPR maintains some form of circulation further
9 digoxin would distribute?

10 A. Yes.

11 Q. So, in other words, the sample
12 that was taken of heart tissue after death we would
13 expect that it would contain some digoxin?

14 A. If that happened you would
15 expect to see some digoxin in the heart, that's right.

16 Q. And what we would expect that
17 over that period, which is one hour and 11 minutes,
18 we would expect that the level of digoxin in serum
19 would be coming down, is that correct?

20 A. Yes.

21 Q. And that the level of tissue,
22 heart tissue would be rising?

23 A. It would be rising or shifting
24 in all tissues and I would expect it to be rising
25 at some rate in heart tissue.

Q. Now, can we go back then and



1

2 could you assist me with the numbers on the board,
3 can you give me your best estimate as to when you
4 think the digoxin was administered?

3

5 THE COMMISSIONER: He's already given
6 that to you.

7

8 MS. SYMES: I want to try and do it
9 in terms of - he said one, two and three hours.
10 Could you just, so I could write it down, on the
11 board.

10

11 A. I think there are a lot of
12 vagaries here. I think it was administered some
13 time, if it caused the initial symptoms at 3:45,
14 it had to be administered some time prior to that.

15

16 Q. What is the outside range
17 that you would place that?

18

19 A. The outside range I would
20 think.

21

22 THE COMMISSIONER: You mean the farthest back?

23

24 THE WITNESS: I am sorry?

25

26 THE COMMISSIONER: You mean the
27 farthest back, the earliest?

28

29 THE WITNESS: Oh, you mean the
30 earliest it could have been?

31

32 MS. SYMES: Q. Yes.

33

34 A. Well, with the concentrations

35



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in serum that were found at 4:30 and the high tissue concentrations in the myocardium the time I gave, and I don't have any reason to depart from that, would be no longer than three hours prior to that simply because it is hard for me to conceive that the baby would not have developed symptoms if it was administered longer than that.

Now, I know that there are cases of babies receiving large doses - well, I don't know what the dose was here.

THE COMMISSIONER: I am sorry, Miss Symes, that is 0045, not 1245.

MS. SYMES: Isn't it the same thing?

THE COMMISSIONER: No.

MS. SYMES: It isn't, is it?

THE COMMISSIONER: No, sorry about that.

MS. SYMES: You're right, 0045, 45 minutes after midnight.

A. I acknowledge that there has been at least one case where the baby received a large dose of digoxin and according to the paper showed symptoms up to eight hours later but I think that is really highly unlikely. The other few cases have been much earlier than that. So, I think we have to stay somewhere in, in all likelihood, a three hour



1

5 2 range prior to onset of symptoms that we could
3 contribute to a toxic dose of digoxin.

4

Q. What is the shortest?

5

THE COMMISSIONER: Could you make it
the earliest and the latest.

6

MS. SYMES: Yes.

7

THE COMMISSIONER: Because I understand
8 that.

9

MS. SYMES: So, this is the earliest.

10

The earliest and latest, sir?

11

THE COMMISSIONER: Yes.

12

MS. SYMES: And what would be the
latest?

13

14

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A. My best estimate as to
latest, and this is difficult. It has to be some-
where before 3:45 if we attribute those symptoms to
it and I think it is possible, probably not so
likely but it is possible with a large dose to see
symptoms 15 to 20 minutes after a bolus, and there
are a lot of variables here. I think it is probably
longer than that but if you want outside numbers that
could include all possibilities I would say the earliest
may be 3:30.

22

23

24

25

Q. Okay. And that is assuming,
that is the important hypothetical, is assuming that



Kauffman, cr.ex.
(Symes)

1

2 what was seen at 3:45 were symptoms of digoxin
3 intoxication?

4 A. Yes, that was what I had just
5 said.

6

7 Q. In that particular example,
8 let's take the earliest, in this particular example
9 would you agree with me that this would have had
10 four hours in which to distribute. At 0045, if
11 digoxin were administered at 0045?

12 A. A little over four hours.

13 Q. It would have been a little
14 over four hours, which would have been the complete
15 distribution in the alpha phase?

16 THE COMMISSIONER: No.

17 MS. SYMES: Well, practically it should
18 have distributed in two and a half hours.

19 A. Distribution following a
20 therapeutic dose at least usually is accomplished
21 by 46 hours; equilibration is accomplished in four
22 to six hours.

23 Q. In this particular case then
24 I understand that as we go on in time less and less
25 is being distributed?

26 A. It tends to become
27 insignificant after a while.

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Q. So that in that period most

of it would have been distributed to the tissues?

A. It would have been distributed

out of serum. I keep saying that because I don't want to convey a conceptual error here. People tend to equate, this has happened in Dr. Hastreiter's paper and I am not criticising him but many other papers too people intend to equate a disappearance from serum to appearance in tissues and they are not the same. That is like sitting at the airport and watching and counting the planes leave and concluding what time they are going to arrive at what destination and it just isn't the same.

Q. I guess like any small child there

is limited places to go and time to get there?

A. There aren't limited places

to go.

Q. Well, in the earliest example

you have given then, most of the distribution from serum would have been completed?

A. That's right. You see, my point is that we can conclude that a half life of disappearance from serum is equal to a rate of appearance in any tissue.

Q. I understand what you are



1

8 2 saying but just in terms of what would still be
3 in serum.

4 A. Yes.

5 Q. Okay.

6 A. Not all that was there is
7 gone, it is equilibrated to what its equilibration
concentration is going to be.

8 Q. Going back to the Hastreiter
9 article, Exhibit 276 on page 282 of that he
10 hypothesizes, doesn't he, that the half life of
11 distribution of digoxin into tissues is 30 minutes.

12 THE COMMISSIONER: I am sorry, what
13 page did you say?

14 THE WITNESS: I am sorry, I am not
15 with you.

16 THE COMMISSIONER: What page, Miss
17 Symes?

18 MS. SYMES: It is Exhibit 276.

19 THE COMMISSIONER: Yes, but what
20 page?

21 MS. SYMES: Just a second. On page
22 483, I gave you the wrong page.

23 A. Yes.

24 Q. Under discussion.

25 A. Right.



1

2

Q. The second full paragraph

3 reads:

4

"Following intravenous administration
the half time of digoxin distribution
in various tissues including myocardium
is 30 minutes."

5

6

A. But that is the point I was
just making. I think that is a naive interpretation
of the pharmacokinetics and I respect Dr. Hastrieter,
I am not criticizing him, but people misuse pharmaco-
kinetic concepts just like they misuse statistical
concepts and this is an example of it. He is
equating disappearance from serum rate constant with
appearance in tissue rate constant and they are
absolutely not equivalent.

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Q. I am sorry, sir, when I

read this I presumed that this was the purpose of
the paper which was to calculate for the first time
distribution of digoxin into tissue.

A. He did not in any way calculate
distribution rates in tissue. He reported a case
in which he was able to quantitate the concentration
in tissue at a finite time after a finite dose of
digoxin but he has no data here with which to make
a distribution rate into tissue with. What he is



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doing is quoting a review article which says the average alpha half life 30 minutes and he is equating it with distribution into heart tissue and it is an error. I don't agree with him.

Q. Well, you must agree that someone not trained in this, to read that, it clearly looks as though he has discovered something new, doesn't it?

A. And the error is perpetuated.

Q. So, you say that that statement, that the distribution of digoxin into tissues of 30 is not correct?

A. I think it is not correct, the assumption is not correct.

Q. And do you know what the right answer is?

A. I do not know, it is different his data suggests that it is different for every tissue.

Q. Yes.

A. But I have no way, and he doesn't, of knowing what it is for each tissue.

Q. Does anybody know?

A. And it is probably widely variable between infants by age and individuals.



Kauffman, cr.ex.
(Symes)

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Q. Does anybody then know what
the half life of digoxin distribution into tissues is?

3

A. To my knowledge, no.

4

5

6

7

8

Q. When you were making your
calculations then with respect to the time of
adminstration basing it on the fact that there was
eleven seventy-seven grams in heart tissue on death
what half life did you assume?

9

10

A. I did not assume a half life
into tissue.

11

12

13

Q. Would it be necessary to do
so to work back from eleven seventy-seven nanograms
per gram to determine the time of administration?

14

15

16

A. No. To calculate the extreme
possibilities it was not necessary to do that and
that's why I didn't calculate any other possibilities
because I had no basis for assumptions to do so.

17

18

19

Q. Dr. Kauffman, can I change one
assumption and, that is, we knew that Justin Cook, we
know from the chart that Justin Cook was a very sick
baby and had had a blue spell at 1800 hours.

20

21

A. The evening before?

22

Q. Yes, shortly before.

23

A. Yes.

24

Q. And that obviously it was a

25



1
2 very severe blue spell and that propanolol or Inderal
3 was given IV and that the patient pinked up
4 immediately. Would you agree with me - I should also
5 tell you that it is our understanding that because
6 of the real concerns about this baby, the baby was
7 placed on constant nursing care, which is one to one
nursing.

8 A. I recall that.

9 Q. Would you agree with me that
10 after 1800 hours this baby was at substantial risk of
11 having a second blue spell?

12 A. I think because of the baby's
13 underlying heart defect he was at a continuing risk
14 for having additional cyanotic episodes.

15 Q. If you look at page 29 of the
chart, which I believe is the nursing note.

16 A. Pardon me until I get the chart.
17 Which place, please.

18 Q. Page 29, sir.

19 A. 29, okay.

20 Q. If you read the nursing note
21 then for her description then of what happens to the
22 baby at 3:45 are the symptoms or clinical observations
23 made at 3:45 consistent with a second blue spell?

24 A. Yes, it is consistent with a



1

2 tet spell.

3

4 Q. If then we change your
5 hypothesis with respect to the calculations and,
6 that is, what is observed at 3:45 is not reaction
7 to digoxin toxicity but instead a second blue spell,
8 would you please do your calculations again as to
what is the earliest and latest times for the
administration of digoxin?

9

A. You mean give estimates again?

10

Q. Please, would you.

11

A. Well, let me see.

12

THE COMMISSIONER: I take it we are
to assume that 4:20 is the first effect of digoxin?

13

THE WITNESS: Well, that was what I
was wondering about. I am not sure that that is what
I want to assume.

16

MS. SYMES: Let's assume then that
this was not, this was just a blue spell.

17

THE COMMISSIONER: Well, we know that,
we know that.

19

THE WITNESS: But I want to see what
was going on in that intervening 40 minutes, or
whatever it is, 30 minutes.

22

MS. SYMES: Q. There is both the
arrest note and the nurse's note. There are two

24

25



1

2 doctors' notes and one nurse's notes on the events. They
3 are found in pages 27 to 29.

4 A. Why don't I start on 27 and
look at them.

6 THE COMMISSIONER: I think we will
rise now for lunch. Have you any thoughts on how
7 much longer you will be?

8 MS. SYMES: I will be quite a bit
9 longer.

10 THE COMMISSIONER: You mean something
11 like several days?

12 MS. SYMES: I have two more children
to discuss; not in as great a detail.

25



Kauffman, cr.ex.
(Symes)

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N/DM/ak

2 MS. SYMES: Well, Mr. Commissioner,

3

4 I don't think that is going to turn out to be that
simple.

5

6 THE COMMISSIONER: All right. At
any rate at the moment now you would like Dr. Kauffman
7 to assume that at 0345 that was just a blue spell,
and whenever he comes to a point where he can say
8 it is not a blue spell it could conceivably be a
blue spell that produced death.

9

10 MS. SYMES: I'm sorry, sir.

11

12

13 THE COMMISSIONER: It could be a
blue spell that produced death at 0345, it could have
been the cause of death, conceivably.

14

15 MS. SYMES: Yes. It is conceivable
that this child died from a blue spell.

16

17 THE COMMISSIONER: Could you just tell
me what you are trying to prove and I will ask
Dr. Kauffman not to listen.

18

19 MS. SYMES: All I am trying to do
20 is to establish "the time window" as Mr. Brown phrased
21 it in which digoxin could have been administered after
3:45.

22

23 THE COMMISSIONER: Yes.

24

25 MS. SYMES: And then the question
will come as to whether or not that could have been



N2

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3 a medication error.

4 THE COMMISSIONER: Well, Dr. Kauffman
5 has in his report given the times, the minimum - the
6 doses and the times he has given all of that, and that
7 is not enough for you.

8 MS. SYMES: Oh, no.

9 THE COMMISSIONER: You wanted to have
10 something else.

11 MS. SYMES: Sir, that was based on
12 one assumption, this is now an entirely different
13 assumption ---

14 THE COMMISSIONER: The assumption is
15 0345 had nothing to do with digoxin, so you are saying
16 digoxin was administered some time after that, is
17 that what you are saying?

18 MS. SYMES: Yes, or that it was
19 administered then or afterwards, yes.

20 THE COMMISSIONER: All right.

21 THE WITNESS: Shall I respond now?

22 THE COMMISSIONER: Well if you can,
23 can you respond to it now?

24 THE WITNESS: I was trying to look
25 and see what had gone on between. The baby apparently
had a seizure shortly after that blue spell and that
very well may have been related, may have been a



Kauffman, cr.ex.
(Symes)

N3

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2 cyanotic seizure, it is hard to know. It could also
3 be a symptom of a bolus of digoxin, but it wouldn't
4 be unreasonable to say it was a cyanotic seizure.

5 Then a number of things happened
6 according to the note. I suspect one of the better
7 chronological descriptions is on page 29. They gave
8 oxygen after the cyanotic spell 100 per cent to breathe,
9 and started to take vital signs. The baby began to
10 have a seizure then which was right around the cyanosis,
11 and that is described. The vital signs at that point
12 were fairly normal. An urgent call was placed and
13 propranolol - on his arrival the physician gave
14 propranolol and I guess that was the first .4 milli-
15 litre dose. Shortly thereafter another dose of .2
16 was given and then the exact time is not here, but
17 the note is the babe's apex then began to dip, it
18 was approximately 72. Because of the bradycardia
19 I assume atropine was given to raise heart rate and
20 then they tried to give morphine, they did give
21 morphine which was an attempt to reduce the cyanosis.

22 Then it looks like things were rapidly
23 progressing over that very minute time, and the baby
24 really continued to be in trouble. So it is hard for
25 me to see a note prior to the arrest at 4:20 that
really - it is kind of a continuum and so it is



N4

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difficult for me to tie it into anything that tells
me anything suddenly changed there.

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You see the event from the cyanosis,
at least my perception is that it was kind of a
continuum, not something suddenly. So it is difficult
for me to give you - I can say if this was a pure
cyanotic spell and the arrest was due to digoxin,
it was administered somewhere in that 39 minute
period and it is hard for me to tie it down more than
that.

Q. That is perfectly reasonable
then. If 0345 was a blue spell, the digoxin could
have been administered any time thereafter.

A. If we say the arrest was due
to the digoxin, I think it is difficult, and this
may be helpful to you, it is difficult for me to
conceive that it was given less than 15 minutes prior
to the arrest, so that would give you a 15 minute
additional window.

Q. So that would be anywhere from
3:45 to 4:05?

A. I don't know whether that is
helpful or not.

Q. Could you just answer the
question, is it possible that this child who had had a



N5

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severe blue spell at 3:45, could he have arrested at
4:20 minus digoxin?

4

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A. Oh I think his severe "Tet" spell could have been associated with an arrest. I think in the absense of any digoxin data that would have been a very reasonable assumption.

8

9

THE COMMISSIONER: Yes, well, now are we satisfied, are you satisfied?

10

11

MS. SYMES: Well he has created a time that it could have been I believe anywhere from 3:45 to 4:05.

12

13

THE COMMISSIONER: Yes. Now are you going to pursue it further?

14

MS. SYMES: Not on that time, no, sir.

15

16

17

18

THE COMMISSIONER: I just wanted to know. What are we coming to? Now you are going to say it was one of the drugs I take it that was administered by error between 3:45 and 4:05, it that it, is that what you are getting at?

19

MS. SYMES: Yes.

20

THE COMMISSIONER: Yes, all right.

21

Well, can we go on then to something else?

22

MS. SYMES: Certainly.

23

24

THE COMMISSIONER: I don't want you to do it now, are we still going to go back on this

25



N6

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thing?

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MS. SYMES: I have two more questions
4 to ask about this.

5

6

THE COMMISSIONER: Let us have them
now so we can at least come back to something else.

7

MS. SYMES: Something new?

8

THE COMMISSIONER: Yes.

9

10

11

MS. SYMES: Q. If this child at
1800 hours, I believe you went through this yesterday,
was given propranolol and it appeared to work very
quickly.

12

13

14

A. That was my impression from
the chart, that the baby pinked up and seemed to
respond to that 1800 hour dose.

15

16

17

18

Q. If the baby, taking your
second hypothesis, at 3:45 was having a second blue
spell, I gather that you would expect that .4 and .2
millilitres of Inderal at 3:45 and 3:55 should have
pinked up the baby?

19

20

21

22

23

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A. Well, I don't know. If the
baby had responded before I think it is a reasonable
assumption that the baby would respond again; but I
don't think it should necessarily be any surprise that
the baby may not respond too.

Q. But normally you would expect



N7

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that if it worked once it should work again?

3

4

A. Well, I don't totally agree with that, you can't always expect that, the patient never responds the same everytime, that is why I said it should be no surprise particularly that the baby may not have responded.

5

6

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Q. But Dr. Kauffman, in a hypothetical, if digoxin were given at 3:45 instead of Inderal, I gather it is clear that you wouldn't expect the baby to pink up?

11

A. No, I wouldn't.

12

13

14

Q. You would not expect the administration of digoxin to this baby to help him in any way?

15

A. I would not.

16

17

Q. And if digoxin were administered at 3:45 instead of Inderal, are the remainder of the notes on page 27, 28 and 29 consistent?

18

A. I'm sorry, if what?

19

20

Q. If digoxin were administered instead of Inderal?

21

A. At 3:45?

22

Q. And 3:55.

23

A. And 3:55.

24

Q. By the results the rest of the

25



N8

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notes, are they consistent?

3

A. I think if you assume that the blue spell at 3:45 was not in any way related to it.

6

Q. That is my assumption.

7

A. That is a given assumption I think the way we are talking now, and could his symptoms have been consistent with a dose of digoxin administered at 3:55, 5 minutes apart under this scenario? I think as I read it that it could be, he would not be expected to respond in terms of decreasing of cyanosis, that would not be inconsistent with his apical rate dip and it would not be inconsistent with the bradycardia later on, 15 to 20 minutes later, and it would not be totally inconsistent with the arrest and the ability to resuscitate the baby.

16

MS. SYMES: Can we take the break then, that is all the questions I have on patient Cook.

19

THE COMMISSIONER: On Cook, yes. Well, I just have one. Is it consistent with the readings that were found?

22

THE WITNESS: No, I don't think so. I consider that and I considered, well I had to consider that the readings that was the thing that

24

25



EMT.jc
AA

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2 --- On resuming at 2:30 p.m.

3 THE COMMISSIONER: Yes, Miss Symes?

4 MS. SYMES: Mr. Commissioner, at the
5 very end of the break or just before the break you
6 asked Dr. Kauffman whether an administration of
7 digoxin at 3:45 and 3:55 was likely, and I believe the
answer he gave was no because of the --

8 THE COMMISSIONER: Whether it was
9 consistent with the readings of digoxin levels.

10 MS. SYMES: Yes, he said in his
11 opinion it was not consistent with the levels of
12 digoxin in tissue.

THE COMMISSIONER: Yes.

14 MS. SYMES: Q. Dr. Kauffman, was that
your --

15 THE COMMISSIONER: No, he said it
16 was not consistent with the digoxin levels - was the
17 question I asked him, and he said no.

18 MS. SYMES: Q. Sir, was it consistent
19 with the level of digoxin in serum?

20 A. If you only had that serum
concentration and didn't have to deal with that
21 myocardial concentration it would be easier to
22 reconcile, yes.

23 Q. Now just so that I can understand

25



AA.2

1

2 because quite frankly your answer puzzles me in light
3 of the previous evidence that you gave to me about
4 the distribution into tissue.

5

6 If the digoxin were administered at
7 3:45 or 3:55, in that range, there would be 1 hour
8 and 11 minutes to distribute or 1 hour and 5 minutes
9 to distribute. Do you agree?

10

A. Yes.

11

Q. And in that time 75% of the
10 digoxin would have left the serum?

11

A. No.

12

Q. The half life?

13

A. That is not 75% of the digoxin
13 in the serum. I thought I explained that this morning.

14

Q. Sir, I am going to do serum
15 first and then tissue.

16

A. Okay.

17

Q. If we have 100 units in serum
18 at the start, after 1 half life we will have 50?
19 Correct?

20

A. Well, are you talking about
20 alpha half life or beta half life?

21

Q. Alpha half life.

22

A. No, that is not absolutely true
23 because as I explained earlier that is a hybrid

24

25



AA.3

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2 constant which includes the disappearance due to
3 elimination as well as distribution.

4

Q. I understood that, sir, and --

5

A. So it would be somewhat less
6 than the amount, and if you had the beta you could
7 feather it out and say - let me show you something.

8

9 If you draw a curve similar to what
10 Dr. Spielberg - you gave us part of Dr. Spielberg's
11 evidence, the exhibit - and you have a curve that
12 is something like this, and you say this is the alpha
13 phase and this is the beta phase.

14

15 This slope here is not truly
16 distribution, and the way you find out what the rate
17 of distribution out is you take the terminal slope
18 that you have and you extrapolate that back to time
19 zero and you measure the difference at each point in
20 time between what the predicted level by extrapolating
21 your beta slope to what it is here, and you will get
22 then a different slope that looks something like this.

23

24 The slope of this actually represents
25 the decline, the rate of decline in concentration
due to distribution, and that is not what we have.
You usually don't differentiate that.

26

27 This curve here represents a combination
28 of distribution and elimination, so if you say that
29

30



AA.4

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2 that slope represents - totally represents only
3 distribution, it is not correct.

4 Q. I understand that, but did we
5 not agree that at the first alpha phase that the
6 distribution predominates over the elimination?

7 A. It is the fastest rate constant.

8 Q. So although my number might
9 be slightly inaccurate in theory one half of the
digoxin in the serum goes out in the first --

10 A. You are half way to equilibrium.

11 Q. Half way to equilibrium, and
12 in 2 half lives I should be approximately three
quarters of the way to equilibrium?

13 A. That is correct.

14 Q. All right. Now that was the
15 half life of the distribution of digoxin from serum.

16 When I asked you about the distribution
17 into tissue I referred you to Dr. Hastriter's article.

18 A. Right.

19 Q. In which he had said that the
20 half life was 30 minutes.

21 A. That is correct.

22 Q. And you told me that was in
error.

23 A. Yes.

24

25



AA.5

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Q. And you told me in fact that no one knows what the half life of distribution into tissues is?

A. Into specific tissues, that is right.

Q. If no one knows what the half life of distribution into tissues is, how can you say with any certainty how much digoxin there would be in the myocardium 1 hour and 11 minutes after a drug had been administered?

A. I think we can say how much would not have been in myocardium. I don't think you can say how much is in myocardium. But at least we know that if we are early into the distributive phase there is going to be very little, and the further we get into the distributive phase there would be more.

The problem is that the so-called distribution out of serum, this so-called alpha half life, is a composite of a whole number - is the sum of a whole number of sub constants. I don't know if you know what I mean.

The distribution of the drug is very complex. It has to go through multiple tissue membranes to get finally to the receptor site. It goes into the serum. It has to go across several



AA.6

1

2 cell layers to get into the extracellular fluid. It
3 has to diffuse across any membrane - wall or membrane
4 as in humans, membrane around the various tissue cells,
5 and even within the cell to get to certain receptors
6 it has to dissolve into subcellular organelles to
7 finally get to the place where it is going to do its
thing.

8

9 So each of those little processes
10 will have its rate constant for movement or active
11 transport or whatever the mechanism is, and all we are
12 saying is that we are describing a whole composite
13 of these. That is why it doesn't say anything to me
14 about the rating at which - we know that this
15 represents some overall rate that the drug is equili-
brating within the body, but we don't know anything
16 about what is happening in a specific tissue.

17

18 It can't be more than this, but it
19 can be considerably less.

20

21 Q. But, Dr. Kauffman, given a
22 dose at 3:45 in the morning I gather the state of the
23 art is such that you cannot say with certainty how
24 much digoxin would be in heart tissue 1 hour and 11
25 minutes later?

26

27 A. I can't give you an absolute
28 number. If you gave me a dose and a time I could tell
29

30



AA. 7

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2 you what fraction of the dose might have been
3 eliminated by that time and what might have been still
4 in the body at that time, but I can't tell you
5 exactly what the concentration would be in any
6 particular tissue at any point in time.

7

I can tell you the likelihood that
it would not be there at, you know, at some time, but
I can't give you specific estimates, no.

9

Q. I presume you yourself have
10 not done this test?

11

A. Which test?

12

Q. That is a loading of digoxin
13 and then measuring heart tissue after death?

14

A. No, I certainly have not.

15

Q. And the only thing we have is
16 the case report which has been marked Exhibit 276 of
Dr. Hastreiter?

17

A. Well, that isn't the only
18 thing we have. We have that and we have a lot of
19 other literature that reports poisoning with tissue
20 and serum levels.

21

Q. But with respect to tissue.

22

A. There is a lot of other tissue
data in the literature.

23

Q. Could we take the one.

24

25



AA.8

1

A. Okay.

2

Q. Which is Exhibit 276.

3

A. Let's look at this one.

4

Q. In that we saw that after 45
5 minutes from administration until death the left
6 ventricle achieved 1252.

7

A. Yes.

8

Q. I believe, Dr. Kauffman, you
9 told me that in heart one would expect that it would
10 continue to accumulate; that is if the alpha phase
11 out of serum is 30 minutes, that you said the heart
12 was a good receptor but a slow one?

13

A. Well, I am postulating that
based on what little I know about it.

14

Q. So we know then if the camera
15 took a picture after 45 minutes of administration that
16 the left ventricle achieved 1252 nanograms per gram?

17

A. From this data we know that
in this patient, yes.

18

Q. And we also know - I mean you
19 are hypothesizing that if the distribution had been
20 allowed to go on a bit further, that the concentration
21 in heart may well increase?

22

A. I think that is possible.

23

Unfortunately --

24

25



AA.9

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2 Q. I'm sorry?

3

A. I was just going to say

4

unfortunately the patient succumbed before that took
place.

5

6

Q. But Justin Cook lived for
another 15 to 20 minutes beyond this example.

7

A. You mean an hour and --

8

Q. An hour and 11 minutes, et
cetera, whereas this one lived only 45 minutes.

9

A. Okay.

10

Q. So given that then, that the
level of digoxin in Justin Cook then may have gone up
from let's say 4:30 to 4:45.

11

A. It may have.

12

Q. But we don't know from the
state of the art of digoxin, we just don't know, do we?

13

A. That is right. But you see
the problem I had if we go with your last postulate
then we have to plug in a much larger dose than my
minimum dose, and that was my dilemma.

14

Q. Dr. Kauffman, the size of the
dose depends very much upon the time at which it was
administered before sampling?

15

A. Yes, because the volume of
distribution that you use in the calculation is much
larger.

16



AA.10

1

2 Q. And in the original calculations
3 that you had done at the very beginning with respect
4 to Cook, the timing that you had assumed was part way
5 down that alpha curve, wasn't it?

6

7 A. Well, I am not sure what you
8 mean.

9

10 Q. When you originally did the
11 calculation with the volume of distribution at 1.3
12 and you got out the doses?

13

14 A. That was assuming early in the
15 alpha curve. Quite early.

16

17 Q. Quite early.

18

19 A. Quite early.

20

21 Q. How early within it?
22 A. Well, I can't tell you how
23 early but early enough that there would be insignificant -
24 there would be an adequate time for a toxic amount of
25 digoxin to get to the receptors in the myocardium.

26

27 Q. Would that be within an hour
28 of 4:30?

29

30 A. Well, I think it could be.
31 That is why I said that I think - going with the
32 scenario that you described --

33

34 Q. The second scenario? That is
35 that 0345 was a blue spell?

36

37



AA.11

1

2 A. Yes, as opposed to digoxin

3

Q. As opposed to digoxin?

4

A. Yes, but the drug could have
5 been given - whether you want to define 3:45 or 4:20
6 as the time of onset of digoxin induced symptoms,
7 that the drug could conceivably have been given 15,
8 20 minutes beforehand. I think that is unlikely but
if we ignore the tissue concentration.

9 You see the problem in accepting that
10 is that there was such a high concentration in the
11 ventricle when it was actually measured, and if you
12 want to posit that that concentration could have
13 occurred in the ventricle in half an hour after the
14 dose was given, you have to postulate an enormous
dose.

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Kauffman, cr.ex.
(Symes)

BB
BB/cr

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2 If you want to --
3 - certainly much larger than what we did
4 the arithmetic on this morning where we came out with
5 a part of an adult vial. If you want to postulate
6 that dose in that time interval you just can't explain
7 a tissue concentration of 1:100.

8 Q. But if we have - I think we
9 have done this before - but if we have an hour and
10 11 minutes to distribute the tissue we may very well
11 get values in excess of those found by Dr. Hastreiter.

12 A. How do you know that?

13 THE COMMISSIONER: Just a moment.

14 Miss Cronk.

15 MISS CRONK: Excuse me, sir. Again,
16 I apologize for doing this all day but I well recall
17 an occasion not many weeks ago when, in discussing
18 the case of Kristin Inwood, I had suggested to another
19 witness that she died at the time that her death
20 was pronounced and I was quite properly chastised by
21 my friend Mr. Roland, and I deserved it at the time,
22 for the error that I made, and it seems to me that
23 that should now hold true for Miss Symes. We know
24 that the arrest for Justin Cook was called at 4:20,
25 we know a sample was taken at 4:30, this witness has
 said that in his view the process of dying could well



1

2 be described to have commenced at 3:45 and onwards.

3 I think if we are going to postulate
4 a time frame then Miss Symes in fairness to Dr.
5 Kauffman has to at least allow for the possibility
6 that the child died before he was pronounced dead.

7 THE COMMISSIONER: I don't think he
8 could have died before 4:20.

9 MS. CRONK: She suggests an hour and
10 11 minutes and that means the child died at 4:56.

11 THE COMMISSIONER: Yes, 4:56, yes.

12 Well, there is that problem, Miss Symes.

13 MS. SYMES: Well, we had established,
14 Dr. Kauffman, that the child's circulation was
15 maintained maybe imperfectly by CPR after 4:20,
16 according to the chart.

17 A. There may have been some
18 circulation. You see, the problem I am having, I
19 pointed out the other day - may I erase your black-
20 board notes?

21 Q. Sure.

22 A. I pointed out the other day
23 that we are talking about a child who had never
24 received digoxin before. So, if indeed a dose was
25 given, as we are talking now, digoxin was, denova
digoxin was going in to the myocardium some time after



1

2 that dose and at some rate that we have no way of
3 measuring. We know how fast, we have an approximation
4 within a range of how fast it distributes out of the
5 serum but we don't know how fast it actually goes
6 into the myocardium. And then we have a gradual
7 rising - let's say this is the heart.

8

Q. Dr. Kauffman, could you do it
8 on the sheet of paper so that we could save it maybe?

9

A. Okay. Let's talk about a
10 hypothetical rise in concentration in the heart after
11 the dose. We won't put units on this because we don't
12 know what it is but we are describing it in general,
13 so, you would expect the total digoxin in the myocardium
14 to gradually rise with time after the dose until it
15 reached some equilibrium after, let's say four to six
16 hours, an equilibrium within the body is established.

17

Now, as I said the other day, the total
18 concentration of digoxin in the heart is comprised
19 predominantly of digoxin which isn't doing anything
20 and which is bound to sites which have lower
affinity than we think the specific active binding
sites have.

21

So, the first drug that gets there,
22 because the affinity constant is so much higher for
23 the specific receptor, the first drug that gets there

24

25



1

2 is going to be attached to those first before any
3 sites get any.

4 So, as the first binding sites with
5 the highest affinity becomes saturated, approach
6 saturation, then drug starts being bound to any
7 sites with the next highest affinity, and you probably
8 have, and I don't know this as a fact but if it's
9 like other situations in nature you probably have
10 secondary and tertiary binding sites which are not
11 active but the drug attaches to them with some degree
of affinity.

12 The drug binds to these sites at a
13 much lower - these sites will all be occupied at a
14 much lower concentration of drug than these sites.
15 So, what you have is the drug, the concentration
16 arising in the myocardium and the first sites that
17 it is going to bind to are going to be the ones
18 which are going to do something to the myocardium
19 cells to change their electrical characteristics
and change their function.

20 After they are approaching saturation
21 then it is going to start binding to other sites.
22 I don't know at what total concentration this child
23 would have achieved a critical level of digoxin
24 which would have produced enough binding to active
25



1

2 sites to have produced toxicity but it would have
3 been at a much lower concentration than this total
4 concentration of 1100.

5 So, it is not a problem to me at all
6 in a kid who did not have any digoxin on board that
7 critical symptoms could show up 15, 20, 30 minutes
8 after a large dose, much longer than what we have
9 been postulating with the minimum dose, and still
10 not have very high concentrations if you took the
11 picture at that point in time if you measure total
12 digoxin, which is what we measured.

13 If you then allow more time, several
14 more hours after the dose we are talking back toward
15 2:30, 1:30, then you have already saturated these
16 primary sites, these high affinity active sites and
17 you are going to have the rest of it distributed
18 into the lower affinity binding sites where it stays
19 until it redistributes to something else.

20 So, there is no problem to me to
21 explain this child developing critical symptoms
22 within 20 or 30 minutes after a large intravenous
23 dose, but it is a problem, a serious problem to me
24 to reconcile that with a myocardium total concentration
25 of 1100 unless you got an enormous dose comparable
to the case described by Dr. Hastreiter.



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Q. Okay. That diagram is very helpful. Does it accurately describe what you have plotted is the concentration of digoxin in tissue to time?

A. Total heart concentration versus some time and I can't put units on it.

Q. And that's because of our lack of knowledge that you can't calibrate the X scale?

A. We don't know what the rate is that this curve describes.

Q. I am going to ask that that be marked as the next exhibit. It may be possible to do a smaller version of it but I think that is very helpful.

THE COMMISSIONER: By all means if you want to have it as an exhibit. I will just tell you it really doesn't help us an awful lot because the Doctor can't tell us what it represents. All it is, it is a curve.

MS. SYMES: It is a curve that rises over time.

THE COMMISSIONER: We have had this sort of curve before, you know, we haven't put it in. We have had this from several witnesses before who have



1

2 said that this is the kind of curve and they weren't
3 able any better than the Doctor was to give the time.
4 He can't tell us, not only can he not tell us what
5 time digoxin gets into the tissue, nor can he tell
6 us which particular tissue it gets into.

7

MS. SYMES: He is talking, sir,
8 particularly the diagram is heart tissue.

9

THE COMMISSIONER: Well, yes, but he
can't tell us that either.

10

11

THE WITNESS: Please, if you do keep
this, please do not attach any quantitative
interpretation to this.

12

13

MS. SYMES: No, that is understood.
THE WITNESS: It is to illustrate a
concept.

15

16

MS. SYMES: Understood.

17

18

19

20

21

22

23

24

25

THE COMMISSIONER: No, we won't erase
it and if it can be somehow or other photographed
and reduced then we will do something with it. Well,
I suppose there is no reason, if you want it that
badly, we just can't take that off now, Mr. Registrar,
and put a number to it and fold it up.

21

22

23

24

25

MS. SYMES: Dr. Kauffman, I had asked
you at the beginning of the day which of the babies
the Police and the Crown Attorney had specifically



1

2 asked you to look for and you had said that you would
3 check your notes.

4 THE COMMISSIONER: What number is that?

5 THE REGISTRAR: 277.

6 ---EXHIBIT NO. 277: Diagram by Dr. Kauffman.

7 THE WITNESS: I apologize, if I have
8 it it will be in the file I am fumbling through here
9 now. It could be one other place and if you bear
10 with me I will look quickly. I vaguely recall having
11 a small piece of paper that I had noted some things
12 down and all I can find now are my handwritten lists
13 of patients who had exhumed tissue concentrations
14 and then the list of the patients that I reviewed for
15 the CDC.

16 Q. Dr. Kauffman, perhaps we could
17 do it from memory then, just in terms of which ones
18 do you remember being asked to pay particular
19 attention to. Was Cook one of them?

20 A. Yes, I am certain that Cook
21 was one of them.

22 Q. Was Lombardo?

23 A. I suspect so but I don't know
24 for certain.

25 Q. Was Pacsai?

26 A. I believe Pacsai was.



1

2 Q. Was Inwood?

3

A. I think so but I am not

4

certain.

5

Q. Was Miller?

6

A. I am fairly certain Miller
was.

7

Q. Was Belanger?

8

A. I believe so.

9

Q. Was Hines?

10

A. I am not certain but I think
so.

11

Q. Was Gage?

12

A. I don't know.

13

Q. Estrella?

14

A. Yes.

15

Q. Gionas?

16

A. I don't know, I don't remember.

17

Q. Okay. Do you recall on

18

Rating No. 1, which of course is the bottom category
on 273, any of those that you were asked to pay
special attention to?

20

A. I believe Onofre may have been
on that list, but again, I am not certain.

22

THE COMMISSIONER: Can you think of
any reason why ---

24

25



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2

THE WITNESS: And Woodcock I think was
on that list.

4

5

THE COMMISSIONER: Why would you have
considered Onofre and Woodcock in your first report?

6

7

THE WITNESS: Well, that's what I am
saying, I think they were on that list because that
list probably influenced me to give a specific written
report on those particular patients.

9

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Kauffman
cr.ex. (Symes)

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2dec83
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DMra

I suspect, although I can't find the list, I suspect that I used that priority list to guide me in which ones to be sure to give something in writing on, and then I probably discarded it afterwards not thinking I would need it in the future.

7

Q. You have given us twelve possibilities.

9 A. Yes, I am sorry, my memory
10 doesn't serve me a year later for that specific thing.

11 Q. I would like to turn now to
12 Allana Miller. I gather on Allana Miller, her chart,
13 I think these are all without question, the only
14 things I am going to put to you, that six hours after
15 her death the digoxin level was taken and that resulted in 78 nanograms per ml. in serum.

16 A. Yes, my report has serum
17 digoxin level obtained six hours post mortem as 78
18 nanograms.

19 Q. And that the tissue concentrations were 5 to 7 nanograms per gram.

20 A. Yes. I believe those were,
21 I have it that those were preserved tissues.

22 Q. And that there was nothing in
23 the lungs.

24
25



Kauffman
cr.ex. (Symes)

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CC2

A. No, I don't have a note here
about the lungs, I would have to refer to the report
to make sure about that. Let me get Mr. Cimbura's
report.

Q. It is on page 5.

A. Okay.

Q. Of the January 11, 1982

Exhibit 95A.

A. Well it says --

Q. You see T10(b).

A. ... 4 nanograms of digoxinlike
substances. No digoxin could be detected."

Q. No digoxin could be detected.

Now I believe that yesterday you said, at page 5690,
Volume 71, that it was your opinion that the
administration of the digoxin was one hour before the
onset of critical symptoms.

A. Excuse me, what page are you
referring to?

Q. Page 5690.

A. Okay.

Q. Now, the critical symptoms I
believe commenced at 1:45.

A. I described 1:45 description
of irregularity in child's apical heartbeat and gagging



1

CC3² and vomiting.

3

Q. And then in Miller we have
whatever we are going to call it, the Code or
resuscitation efforts ceased at 3:27.

5

THE COMMISSIONER: Yes, Miss
6 Jackman?

7

MS. JACKMAN: There was a further
8 explanation of what was said on 5690 by the doctor,
9 on 5691, and perhaps it should be put to him as well.

10

THE COMMISSIONER: Yes, than, you.

11

What volume is this?

12

MS. SYMES: This is in Volume 71,
13 Mr. Commissioner.

14

THE COMMISSIONER: Yes, 5690, 5691,
yes, all right.

15

MS. SYMES: Q. Then the question is:

16

"Q. Doctor, is it then your best

17

judgment, bearing in mind that the

18

gagging, the vomiting and the brady-

19

cardia that you have mentioned are

20

recorded as having occurred or at

21

least starting to occur at 1:45 in

22

the morning, is it then your best

23

judgment that this dose would likely

24

have been administered about an hour

25



CC4

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before that time?"

2

A. I'm sorry, where are you reading?

3

Q. 5691.

4

A. Okay.

5

Q. "A. I can't be precise about the hour but I would agree that it was most likely administered prior to the onset of those symptoms which appear to be the beginning of a series of worsening symptoms."

6

Is that fair? So is that the

7

benchmark we take then 1:45, an hour before that?

8

MS. CRONK: Well, read the last sentence, Ms. Symes.

9

MS. SYMES: Q. "...It could have been as early as 30 minutes, maybe probably within an hour."

10

A. "...maybe probably within an hour."

11

I think what I --

12

Q. And on the next page just to complete:

13

"...I gave outside numbers of 60 to 90 minutes to be generous but I really believe it was probably shorter than

14

15



1
2 CC5 90 minutes."

3
4 Q. So that would have been 30 to
5 60 minutes before 1:45?

6 A. If you take the range of what
7 I have said I could live with it most comfortably.

8 Q. So that would either be at
9 12:45 -- Oh, I'm sorry, that is 0045 or 1:15.

10 A. I think that is correct, that
11 is 30 minutes before to maybe an hour before.

12 Q. And this baby then got into
13 difficulties but continued to be treated until 3:27,
14 is that correct?

15 A. I don't have that in front of
16 me.

17 Q. I believe it is in the chart,
18 page 42 of the chart of Allana Miller.

19 A. Page 42?

20 Q. Page 42 of the chart, I am just
21 reading the notes of the nurse who was recording it.

22 A. At 1:45 her apical rate was
23 irregular and decreased, then she -- she had the
24 gagging and vomiting, very thick clear mucus, was
25 suctioned; she received 6 mg. of Lasix at 2:40 and
then she began to have a seizure and there was no



Kauffman
cr.ex. (Symes)

CC6

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heart rate; then CPR was initiated I assume very shortly after 2:45 and then she was pronounced dead at 3:27.

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Q. Again, in terms of the timing that you have given; if we take the administration of the drug from 0045 to 1:15 to 3:27, that is if the drug had that long to distribute, that is at least a minimum of three hours to distribute, would you agree?

10

A. Yes.

11

12

13

Q. Which according to the distribution from serum that it should have been almost completely distributed?

14

A. That is true, or at least almost 90 per cent, 85 to 90 per cent.

15

16

17

18

Q. And again going back to that Hastreiter caper, if digoxin had been given and given three hours to distribute, would you not have expected to see that in tissue?

19

A. Well, there was some in tissue.

20

Q. Would you not have expected a lot more in tissue?

21

22

23

24

A. It would depend on the dose she got. If you postulate an enormous dose, then, yes the closer to the time of death you postulate the dose

25



Kauffman
cr.ex. (Symes)

CC7

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2 being given the higher the dose you have to postulate
3 to get higher concentrations in tissue. You see the
4 concentrations in tissue are not only a function of
5 time, they are a function of the quantity that is
6 placed there to diffuse into the rest of the body.

10

7 Q. I understand that, doctor, but
8 it was your hypothesis, or your best opinion that the
9 drug would have been administered from 0045 to 1:15,
10 which you have agreed is at least three hours before
3:27.

11

A. That is right.

12

13 Q. And all I am saying is in that
14 amount of time, if we look at the Hastreiter example,
15 wouldn't we expect to find over a three hour period
16 of distribution digoxin in tissue of the heart?

17

A. Yes, we would.

18

19 Q. And would we expect, if a
fairly large dose of digoxin was given at 0045 or
1:15, that the digoxin level in tissues would be
relatively large?

20

A. Yes, that is true too.

21

Q. Because we don't find that --

22

A. We don't? I didn't have,
the reason I asked that is that the fixed tissue,
I really can't put a quantitative value on that. I

23

24

25



Kauffman
cr.ex. (Symes)

1
2 CC8 said in my report and said earlier this week that
3 about all I can do with that is to say that it is
4 there. How much more, I think that represents the
5 least it could have been, but how much more than that
6 I can't say.

7 Q. Would it be times 2?

8 A. I don't know.

9 MR. HUNT: Mr. Commissioner, Mr.
10 Scott went over this matter in tremendous detail
11 yesterday, and in my submission it is just repeating
12 it unless there is a new point to be made.

13 MS. SYMES: Q. I am simply trying
14 to -- I am going to move on to something that certain-
15 ly Mr. Scott did not talk about. My question to you
16 is, you said that in the Miller -- because the levels
17 of digoxin are in fixed tissues, it is difficult to
18 make very solid predictions about what happened in
19 this particular case.

20 A. It is difficult to know what
21 the concentration in the heart was.

22 Q. Is it also possible, Dr.
23 Kauffman, that your time estimates may be wrong, and
24 that is the digoxin could have been given much closer
25 towards death?

A. I think that is a possibility



Kauffman
cr.ex. (Symes)

1

CC9 2 if you can define death, the time of death for me.
3 If you can agree with me -- and I am not suggesting
4 one or the other, because death in this kind of
5 situation for me is very difficult for me to define.
6 If we can agree on a time for death, my answer to that
7 would be, I think the dose could have been given as
8 soon as approximately 15 minutes prior to whatever
9 we call death, or maybe up to 30 minutes to 60 minutes
10 at the outside before death, looking at this picture.
I don't know when she actually died.

11 Q. Dr. Kauffman, let's look then
12 at the Allana Miller chart. Again on that same page
13 that I referred you to, page 42, we know that the
14 child got into difficulty at 2:45; at approximately
15 2:45 the baby began to seizure and become rigid and
16 then we have a Code 25 called. Do you see where I
am reading?

17 A. Yes.

18 Q. If we postulate that death
19 occurred at 2:45 to 3:27, that is anywhere in that
20 period of time --

21 A. So we ignore the earlier
22 symptoms at 1:45?

23 Q. No, if we say that death
24 occurred --

25



CC10

1 A. At 2:45?

2

3 Q. Sometime between 2:45 and 3:27.

4

5 A. Okay.

6

7 Q. Are you saying then that it
8 is a possibility that the digoxin could have been
9 given 15 to 30 minutes before that?

10

11 A. If we ignore the earlier
12 symptoms as being the first symptoms of digoxin
13 intoxication; and this is the same problem we have
14 with Cook I think a little earlier, is whether or
15 not we assume those earlier symptoms were due to the
16 heart disease or to the effects of a large dose of
17 digoxin.

18

19 Q. For example, if digoxin were
20 given say at 2:40, and we take the same error theory
21 that was put to you, that is that the Lasix which was
22 .6 of a milligram was instead --

23

24 A. .6 millilitres. It was 6 mg.
25 and it is 10 mg. per millilitre so it would be .6
millilitres.

19

20 Q. And the baby then weighs
21 6 kilograms, and you used one then on page 5703 of
22 your evidence in Volume 71 to calculate, to use,
23 pardon me the equation.

24

25 MR. HUNT: Would you wait for the



Kauffman
cr.ex. (Symes)

1

CC11 2 witness to get the transcript.

3

4 MS. SYMES: I'm sorry. Volume 71,
5 page 5703, where you are doing the calculations on
Miller.

6

A. Okay I have it now.

7

8 THE COMMISSIONER: I'm sorry, the
page again was, oh, Volume 71, I'm sorry I had the
wrong one.

9

10 MS. SYMES: Q. In the equation
11 then you plugged in 6 kilograms for weight, 1.0 as
12 the volume of central distribution and you calculated
13 then if the dose was 150 that the concentration had
14 to be 25 nanograms per ml.

15

A. In serum?

16

Q. In serum, sir.

17

A. Yes.

18

19 Q. And then you said at page 5707
20 that that would require a multiplier of about 3 times
21 in order to achieve the 78 which was in fact found,
22 and you said that was somewhat unlikely, have I
23 fairly summarized what you said?

24

25

A. I said: "And if you can
accept a multiplier threefold which I think is in the
realm of possibility and obtaining the sample as early
six hours after death I think that is somewhat unlikely."



Kauffman
cr.ex. (Symes)

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CCL2 2

Q. Now --

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A. I think what I was referring
to, the unlikely I was referring to, is you would have
that large a multiplier 6 hours after death.

5

6

7

8

Q. Dr. Kauffman, if we instead
change the volume centre of distribution as we did
in the Cook case, that is we take the .6, 0.6 or 0.8
and we redo the calculations --

9

A. Yes.

10

11

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DD/EMT/ak

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Exactly the same assumptions, sir, only we change
the volume of central distribution.

3

4

5

6

If we do .6, changing nothing in your
equation except that, I believe your concentration
turns out to be 41.67 or 42.

7

A. This is my calculation?

8

Q. No, this is my calculation
using the exact same equation that you used before.

9

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A. Okay. I would have to go
through it all. I made an error when we did this
before and I don't want to do the same thing again.
I chose one - let's see, that would be --

Q. Your choices were 150 equals
the concentration times 1 times --

A. Yes.

Q. -- times 6.

A. Yes. I just did the arithmetic
on my calculator. I agree with you.

Q. You agree with me?

A. Yes.

Q. If the volume of central
distribution is 0.8 then the concentration is 32.
Would you check my arithmetic?

A. It is in between so I will
accept that it is approximately correct.



D2

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Q. If the first is so the multiplier then to reach 78 is less than 2?

A. That is correct.

Q. And if we use the second - the multiplier is about 2.4.

A. I believe - you mean the .8 or the .6?

Q. 0.8, sir.

A. It would be approximately 2 to get to 70.

Q. Are those multipliers more realistic given that the sample was taken six hours after death?

A. Well, that is difficult to answer because as you know the multiplier, the so-called multiplier, this increase in concentration post mortem is so variable.

Q. Yes.

A. So I suppose the trend would be that you would have less of a multiplier with a shorter time. That is what I was suggesting a moment ago.

The problem I have with these assumptions, apparently the .6 is that this is a number that has been reported with premature infants and



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3 Miller was an 11 month old girl.
4

Q. I agree.

5 A. So she really doesn't fit. I
6 mean we are comparing her to a different population
7 of information.

8 Q. But if we use the .8 the
9 multiplier comes down considerably.

10 A. Yes.

11 Q. And if we were to - using the
12 same assumptions then does it then become more
13 plausible, in fact even probable that the levels in
14 Estrella of digoxin found in serum, 78, six hours
15 after ---

16 MR. YOUNG: We are talking about
17 Miller.

18 MS. SYMES: Oh, I'm sorry, Miller.

19 Q. Six hours after death could be
20 accounted for if digoxin had been given for Lasix at
21 about 2:40.

22 A. I think it is within the realm
23 of possibility given all the caveats that we have
24 just mentioned.

25 Q. And, Dr. Kauffman, I would
like to ask you about patient Inwood now.

First of all on 95 - I ask you for



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two things. First of all the report of Mr. Cimbura,
95A on page 7, lists the concentration of digoxin in
heart tissue.

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And Dr. Kauffman, those values in
themselves on T8 are within normal range?

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A. Well, I don't know that I
said that. I am not sure that we can say that since
it was in fixed - it was from fixed tissue.

10

11

12

If you took those numbers listed in
T8A and accepted those as fresh tissue concentrations,
they would fall within the range of concentration
described in patients on therapeutic doses.

13

14

15

But I think this was in fixed tissue
so it is difficult to answer that question with any
confidence.

16

17

Q. In other words, you can't say
one way or another whether or not they are within
normal range?

18

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A. Well, I just said if you accept
them as being from fixed tissue - I will try to be
more helpful and answer you to this extent, and
hopefully not get myself into too much trouble, and
that is if we accept the report of the concentration
of digoxin, not the digoxinlike substances but the
lower concentration, and if we will accept that that



DD5

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2 is the least that was there, when the tissue was
3 fresh, there was somewhat more but we don't know how
4 much more --

5 Q. Yes.

6 A. If that was the least that
7 was there it was at least that high, so viewing those
8 numbers they fall within a so-called therapeutic
9 range that has been reported. But I have reservations
10 about saying that to you because we don't know how
11 much the levels may have been because of the problems
12 with the fixative that have been discussed.

13 Q. And if we turn to --

14 MR. OLAH: Mr. Commissioner, in all
15 fairness to this witness he has previously indicated
16 that he agreed with Mr. Cimbura's figures on page 4
17 on dose number 3, and that suggests that the toxic
18 range commences at a low of 108 up to 1240, and I
19 think --

20 THE COMMISSIONER: But they are in
21 both I think, aren't they?

22 MS. SYMES: Yes.

23 THE COMMISSIONER: Aren't they in
24 both the toxic and therapeutic?

25 MR. OLAH: That is correct.

MS. SYMES: Q. Now on 95C which is



Kauffman, cr.ex.
(Symes)

DD6

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the report of Mr. Cimbura dated March 25, 1982, there
is a sample called T46. Do you have it?

3

A. Yes, I have that.

4

Q. That is described in this
report as reported to be serum, and I gather that
there is some question about this sample.

5

MS. CRONK: Is my friend suggesting
the sample is not serum because if she is --

6

THE COMMISSIONER: No, I think not.

7

We went through all of that but there certainly is
some question about this.

8

MS. CRONK: I am getting paranoid.

9

MS. SYMES: Q. Now the question
about this sample, as I understand it, is that it
would have been taken some time around the 13th of
March, 1981 because that is when she died, Inwood,
and that it was given to the Centre for Forensic
Sciences on the 28th of January, 1982. That is
some 10 months later.

10

Is that your understanding as well?

11

A. I knew it was some months. I
didn't know how many months.

12

Q. Well, T46 --

13

THE COMMISSIONER: Well, if you
will accept that.

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7 THE WITNESS: I will accept that.

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MS. SYMES: Just above that it says
it arrived January 28, 1982.

5

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THE WITNESS: I will accept that if
nobody has any objections to my accepting it.

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EMT.jc
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Q. So it is some 10 months. And
we understand then that it was subject to freezing?

3

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A. Well, I wasn't sure. I had
said the other day I didn't know --

5

6

Q. What had happened to it?

7

8

A. Whether it had been frozen,
refrigerated, both or so forth. I really can't
comment on how it was handled other than to say I was
told there were some uncertainties about it.

9

10

Q. All right. Now because of
that uncertainty, Dr. Kauffman, I understood you
divided by 10?

11

12

A. That is what I did in my
estimate.

13

14

THE COMMISSIONER: If you divided by 10.

15

MS. SYMES: Pardon?

16

17

THE COMMISSIONER: I don't think he
divided by 10. He said even if you divide by 10.

18

19

THE WITNESS: Yes. The context of
my comment was, it is terribly high. Even if you
divide it by 10 it is still at a level that would be
potentially toxic.

20

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MS. SYMES: Q. But, Dr. Kauffman, I'm
sorry, I have no idea why you would have picked 10.
Why didn't you pick 100?

22

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DD2-2

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A. I picked 10 because I thought
it was such an extreme number that nobody could have
any doubt that it could be a greater divisor than that.

3

4

Q. Well --

5

6

A. In my mind I felt that was an
extreme assumption.

7

8

Q. But, Dr. Kauffman, I tell you
now about the quality of my housekeeping. If I put
a glass of milk in the fridge it doesn't seem to me
to take very long until it evaporates.

9

10

11

12

A. I have never done that
experiment.

13

MR. OLAH: We are talking about freezing.

14

MS. CRONK: It has nothing to do with --

15

MR. OLAH: What we were talking about
was freezing, not with evaporation.

16

17

18

MS. SYMES: Q. Now if we put a tray of
ice cubes in a freezer, do you agree that the water
evaporates over time?

19

20

21

A. I can tell you I have had ice
cubes in my freezer all winter and they are still
there in the spring. I haven't seen a tray of ice
cubes evaporate yet.

22

23

Q. You haven't?

24

A. No.

25



DD2-3

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2 Q. So you are saying --

3 A. And I have a defrosting freezer.

4 MR. OLAH: Excuse me, Mr. Commissioner

5 THE COMMISSIONER: I think it is

6 better if - the old cliche about apples and oranges:

7 can we not ask about blood, what happens to blood. He

8 is more likely to have it - I shouldn't say this,

9 Doctor. You may well have more experience with ice

10 cubes but I would think he had more experience with

11 blood than ice cubes.

12 MS. SYMES: Q. Dr. Kauffman, have you

13 MR. OLAH: Before my friend proceeds,

14 Mr. Commissioner, may I register my further objection?

15 We had evidence that there may or

16 may not have been a stopper on this container, and in

17 all fairness to the witness in my respectful

18 submission it behooves the examiner to indicate all

19 the facts that we have had before the court.

20

21 THE COMMISSIONER: Well, if all the

22 facts that she can give are that there may or there

23 may not have been a stopper that won't help him an

24 awful lot.

25

MS. SYMES: No.

26

27 THE COMMISSIONER: I wouldn't think,

28 however, I think you probably know as much about the

29

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DD2-4

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2 sample as we do, do you?

3 THE WITNESS: I don't know if I do or
4 not because I don't know how much is known outside
5 of my own knowledge.

6 MS. SYMES: Q. I think that the bottom
7 line is that no one knows very much about it except
8 that it was kept for 10 months.

9 It may have had a stopper on it; it
10 may not have. It may have been frozen. It also may
11 have been heated, and that is found in Mr. Cimbura's
evidence, Volume 52, pages 1656 and 1657.

12 THE COMMISSIONER: But Mr. Cimbura
13 doesn't know any more about it than we do.

14 MS. SYMES: No, but he is saying it
15 may not only have been frozen but it may have been
heated.

16 THE COMMISSIONER: It may have been
17 taken up to the top of Mount Everest too.

18 MS. SYMES: Unlikely.

19 THE COMMISSIONER: But I don't know
20 what effect that would have on it too. But we just
21 don't know what happened. I don't believe there has
22 been any evidence of what happened to it except that
23 we did have a great fight as to whether it was blood
or serum and finally it was decided it was serum.

24

25



Kauffman, cr.ex.
(Symes)

DD2-5

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2 I think we took the evidence, not on
3 oath, of Mr. Roland to that effect if I remember.

4 MS. JACKMAN: Mr. Commissioner, I have
5 in my notes although I don't have the page that
6 Dr. Ellis had said it was heated.

7 THE COMMISSIONER: All right. That is
8 good. Then we have that.

9 MR. SHINEHOFT: Mr. Commissioner?

10 THE COMMISSIONER: All right, Mr.
11 Shinehoft has something to say.

12 MR. SHINEHOFT: I think there were
13 some experiments performed by Mr. Cimbura on heated
14 samples.

15 THE COMMISSIONER: Yes.

16 MR. SHINEHOFT: And the conclusion
17 was that it didn't make any effect whatsoever.

18 THE COMMISSIONER: Yes, I think I
19 remember that too. Anyway, somebody has told us it
20 was heated. It was kept for 10 months. And anything
21 else that you want to offer to him?

22 MS. SYMES: Q. Yes. Dr. Kauffman, if
23 evaporation takes place due to freezing or sitting
24 out, that would raise the apparent concentration, do
25 you agree?

A. If that occurred it would have



DD2-6

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2 the effect presumably of raising the concentration,
3 yes.

4

5 Q. If the sample were heated and
6 liquid were driven off in the process of heating,
7 would that also have the effect of raising the
8 apparent concentration?

9

10 A. If there was some evaporation
11 and no breakdown of the digoxin due to the heating
12 you would expect the concentration to increase to
13 some degree. I don't know to what degree.

14

15 Q. Dr. Kauffman, given that
16 both of those may have happened to the sample, do
17 you have any confidence in the level of 491 whether
18 it is divided by 10 or 20 or 50?

19

20 MR. OLAH: Excuse me, Mr. Commissioner,
21 I am sorry, I must object again.

22

23 We have had evidence by Mr. Cimbura
24 where he has carried out a survey to duplicate the
25 situation in here, and the evidence before this court
is that there was no alteration as a result of the
heating, so with the greatest respect to put that
evidence to the witness is just not fair.

26

27 MS. SYMES: Just a second. The
28 question is not with respect to - the question that
29 I asked Mr. Cimbura was about the breakdown of digoxin.

30

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DD2-7

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2 I am not touching that. I am only asking about
3 evaporation of the liquid in which digoxin is.

4 MR. TOBIAS: My recollection of the
5 evidence of Mr. Cimbura is that that very scenario
6 was put to him, an honestly identical question.

7 THE COMMISSIONER: But, Mr. Tobias,
8 the same question can be put to this witness. It is
9 a perfectly legitimate question to ask.

10 MR. TOBIAS: But in fairness should
11 not he evidence that has already been put before the
12 Commission be put to the witness?

13 THE COMMISSIONER: Well, when he
14 talks about evidence. I know of very little evidence
15 except that we don't know what happened to this
16 particular sample the 10 months that it was ...

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MR. TOBIAS: But the witness is
being asked to give a conclusion based on a hypotheti-
cal set of facts which he has already said couldn't
have taken place.

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MS. SYMES: Well, just a second, how
can you say that?

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THE COMMISSIONER: Well, I don't

know that couldn't have taken place. I am going to
allow you -- would you try your question once more
and we will see what the doctor has to say.

MS. SYMES: Yes.

Q. Dr. Kauffman, if this sample

had been frozen, if the sample had been heated, if it
had been kept with or without a stopper for ten
months, could you put any degree of reliability on
the figure of 491 nanograms per ml. whether it is
divided by 10 or 100?

A. I did and I still do. I

reduced it by what I thought was an extreme amount
and said it is still high and I think it probably
was really something more than what I concluded from
that extreme assumption but I was trying to give the
benefit of the doubt to the situation.

I can tell you that we routinely

store biological samples in my laboratory for several

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EE2 2 years and reassay them again for certain things. Now,
3 some things aren't stable but you do not see with
4 many things, assuming the compound is stable, storing
5 something in a freezer is not in and of itself for
6 several years necessarily, does not necessarily cause
7 a change in concentration. In fact, that's what we
8 use to store biological samples that we may want to
analyze later on.

9 Now, if you store the container
10 open you may get some evaporative loss over a period
11 of time and I can't really tell you rapidly because
12 I haven't done specific experiments but I can tell
13 you if the container is closed, the sample will keep
14 several years in terms of volume. If you have the
15 container open there may be some evaporation and when
16 I thought about all of this back when I was doing
17 this exercise I thought, well, it is unlikely,
18 extremely unlikely in my mind that the volume would
19 be reduced by tenfold over a period of months even
20 if the container was uncapped, and those are the
21 reasons why I went through this exercise.

22 I must tell you, I didn't really
23 think that sample, if it was frozen for some months,
24 reduced its volume by tenfold, but I thought that I
25 would make that assumption to give my calculation the



Kauffman
cr.ex. (Symes)

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EE3 2 benefit of the doubt, and I still came out concluding
3 that that concentration was high.

4 Q. If the sample were kept in this
5 sort of imprecise way, is it also possible that there
6 could be an artefact present in it if the sample were
7 kept open?

8 A. I guess anything is possible.
9 I can't think of what kind of artefact or why it would
10 be induced or anything like that but, you know, I
11 hesitate to say. I am probably not going to say
12 any time during this testimony that something is
13 absolutely impossible but I have no basis at all unto
14 which to agree with you that there would have been
15 an artefact, I just don't know of any reason to
16 assume that.

17 Q. It's not the best sample from
18 which to draw conclusions?:

19 A. It is certainly not an ideal
20 sample.

21 Q. Now, this child Inwood, I
22 gather that she had been on digoxin --

23 THE COMMISSIONER: Are you fairly
24 close to the end of Inwood because I thought we might
25 take a break sometime.

26 MS. SYMES: Certainly, sir.

27

28

29



Kauffman
Cr.ex. (Symes)

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THE COMMISSIONER: Well, no, when
it is convenient.

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MS. SYMES: This would be convenient
now, sir.

5

THE COMMISSIONER: How much longer
do you think you will be?

7

MS. SYMES: I am almost done with
this witness.

9

THE COMMISSIONER: With this witness?

10

MS. SYMES: I would say fifteen
minutes.

11

THE COMMISSIONER: Yes. All right.
Yes, Mr. Tobias?

13

MR. TOBIAS: Mr. Commissioner, it
would be helpful to me if you could give some indica-
tion as to how late you intend to sit this evening?

16

THE COMMISSIONER: Well, I am going
to be held personally responsible if Dr. Kauffman
does not get his plane at seven o'clock I can tell
you that. So, we obviously will not be sitting past
five.

20

MR. TOBIAS: Thank you.

21

THE COMMISSIONER: And I don't think,
I think the only thing I can do is if there is
somebody -- the tentative date is the 19th of

24

25



Kauffman
cr.ex. (Symes)

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2 December, which is a Monday. Is there anyone who
3 can now say that he will not be available on the
4 19th? You won't?

5

MR. SHINEHOFT: That is correct.

6

THE COMMISSIONER: You seem to be
the only one.

7

MR. SHANAHAN: 19th, sir, for this
witness to return?

9

THE COMMISSIONER: Yes.

10

11

MR. SHANAHAN: A terrible day for me,
especially if we hit the point today where it is
just the parents left.

12

13

THE COMMISSIONER: Well, we are
not going to get to that point because we are still
going to have Miss Jackman and Mr. Olah and the
parents but the real problem is I have more or less
undertaken to Dr. Kauffman that he will be here just
for one more day.

18

19

MR. SHINEHOFT: I will be out of
the country that day, sir.

20

21

THE COMMISSIONER: You are leaving
the country?

22

MR. SHINEHOFT: Yes.

23

MR. SHANAHAN: That's a good day to
bring him back.

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EE6

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THE COMMISSIONER: Well, I wonder if we could ask you to stand down and we will try Mr. Shinehoff and Mr. Shanahan. We will give you another fifteen minutes, we will even extend that to half an hour on the 19th if you are available.

MS. SYMES: That is perfectly agreeable, sir. It would probably make sense if I could just finish the question on Inwood which would be very brief.

THE COMMISSIONER: Well, all right, do you want to do that now before we break off?

MS. SYMES: Yes.

MR. SHANAHAN: Mr. Commissioner, if this witness is back on the 19th, where are we today?

THE COMMISSIONER: We are at 180 Dundas Street West.

MR. SHANAHAN: No, no, who is left? We have Miss Jackman and Mr. Olah.

THE COMMISSIONER: Well, but also remember we have Mr. Hunt and Miss Cronk waiting in the wings and they will probably take I would think between them half a day. So, there is the problem.

Now, you say you are not available on the 19th?



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EE7

2 MR. SHANAHAN: The morning of the
3 19th I am not but if I was taken out of order I would
4 obviously be all right.

5 THE COMMISSIONER: Well, if you
6 were taken now because in the morning, you see, if
7 you are not available in the morning, by the afternoon
I hope to be well into re-examination.

8 MR. SHANAHAN: Well, let's see
9 what happens over this break here.

10 THE COMMISSIONER: Yes, all right.
11 Well, we are not going to have the break until after
12 you have finished with the Inwood child.

13 MS. SYMES: Q. Do you have the
14 Inwood chart, Dr. Kauffman?

15 A. Yes.

16 Q. Could you turn to page 12 of
17 that chart, please. All I want to establish is that
18 this child, Baby Inwood, was on digoxin and had been
19 on it for eleven days prior to her death. I think
20 that she was first digitalized on February 28, 1981
21 at the Toronto East General before she came to The
Hospital for Sick Children.

22 In addition, we have on page 55 of the
23 chart that she is to be continued on digoxin, and on
24 page 75 of the chart, we have the digoxin order as

25



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EE8 2 .006.

3 A. I'm sorry, which page?

4 Q. Page 75 of the chart, the
5 doctor's order.

6 A. Yes.

7 Q. It is the third one. It is
8 .006 mg. by mouth twice a day.

9 A. Right.

10 Q. So, this child then being on
11 digoxin for eleven days would have had a build-up
12 in her tissues. Do you agree with me?

13 A. Yes, she would have had a
14 gradual buildup in her tissues.

15 Q. And we know that on the 12th of
16 the third 1981 at 5:30 in the morning a medication
17 error occurred, and that is part of the chart, it is
18 Exhibit 113A. Maybe I will just tell you this, I
19 don't think it is in dispute, she was given Pacsai's
20 dose of digoxin and Pacsai was on 0.02 mg. by mouth.

21 A. Yes, I was aware of that.

22 Q. So, this child then would have
23 received .02 mg. of digoxin at 5:30 in the morning.

24 A. .02.

25 Q. .02 mg. of digoxin. So, we
would expect then that digoxin would be in tissues,



Kauffman
cr.ex. (Symes)

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EE9 2 wouldn't we?

3 A. Yes.

4 Q. From her regular maintenance
5 dose we would expect digoxin to be in tissues?

6 A. Yes.

7 Q. And in addition because of
8 the overdose that she received 22 hours before death,
9 would that partially explain the levels in the
tissues?

10 A. Well, I think that would be
11 consistent with levels in her tissues.

12 Q. Would that mean that because
13 she had received the overdose 22 hours before death
14 that it wouldn't be surprising the levels in tissue
15 were slightly high, on the high side of normal?

16 A. I think she had her digoxin
17 doses held subsequent to that.

18 THE COMMISSIONER: Yes, she did.

19 THE WITNESS: So, there was nothing
20 given after that error?

21 MS. SYMES: Q. After 5:30 in the
22 morning, that's right.

23 A. That's correct.

24 Q. And she died in fact somewhere
25 about 22 hours after that.



EE10 2 A. And that dose that was given
3 in error was something like three times her usual
4 maintenance dose if I am not mistaken.

Q. .02.

A. And she was on .006.

Q. That's right, three times,
an three times.

A. That's right. So, with all the vagaries of fixed samples and an eightfold range of acceptable therapeutic concentrations in tissue, it is hard to say whether this represented a higher concentration in her tissues or not. I would guess that because equilibration would occur over that 20 hours that the concentration in her tissues must have been somewhat, a little bit more than what was there before she received that dose, obviously.

16 Q. Dr. Kauffman, if we are forced
17 to discard that T46, the one that we talked about in
18 Inwood as an unreliable sample, that is, that nothing
19 can be drawn from it --

20 THE COMMISSIONER: You are now talking about the serum reading?

MS. SYMES: Yes, sir.

THE COMMISSIONER: Yes.

MS. SYMES: The serum reading.



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EE11 2 THE COMMISSIONER: Don't say if we
3 are forced, say, let us say, let us assume.

4 MS. SYMES: Q. Let us assume that
5 we can place no reliability on T46 and then the
6 levels we have for Inwood are only the ones that I
7 had read you --

8 THE COMMISSIONER: That's the
9 tissue levels?

10 MS. SYMES: The tissue levels.

11 Q. -- what category would you
12 put Inwood in?

13 A. Well, I think I had her in
14 category 2 originally based on those assumptions
15 before I had that information.

16 Q. So, can I fairly say that
17 Inwood would go from a 4 to a 2?

18 A. She went from a 2 to a 4,
19 so, I guess she would go back again if we discarded
20 that level.

21 MS. SYMES: Okay. That is the end
22 of Inwood.

23 THE COMMISSIONER: Yes, all right.
24 Well, we will take fifteen minutes
25 now.

26 --- recess.

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---Upon resuming.

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THE COMMISSIONER: Now, Mr. Shinehoft, how long will you be?

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MR. SHINEHOFT: 15 minutes to half an hour, Mr. Commissioner.

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THE COMMISSIONER: All right, we will see then.

CROSS-EXAMINATION BY MR. SHINEHOFT:

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Q. Doctor, my name is Jack Shinehoft and I represent the parents of the Baby Kevin Pacsai. I understand, Doctor, from the evidence you have given us and from your curriculum vitae that you are both a clinical pharmacologist and a pediatrician, is that correct?

A. That is correct.

Q. Could you tell us, please how much of your practice is associated with each of those disciplines?

A. It is hard to separate it, but I spend about one-third of my time during the calendar year in full time patient care, not all at the same time, but I would guesstimate it that way.

My research is all clinically oriented, so it is patient, this involves patient care also. So there is a lot of overlap, so it is hard to sort



Kauffman, cr.ex.
(Shineholt)

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3 it out. My clinical pharmacology consulting of
4 course is patient care. So I see patients on a
5 regular basis, but my full time care of patients is
probably a third of my time.

6

7 Q. And that consists of the day-to-day treatment of babies, is that correct?

8

A. Of infants, yes.

9

10

Q. As part of your educational background and your studies, does it include the study of endocrinology?

11

12

13

14

A. Only to the extent that any pediatric resident and medical student would have some instruction in endocrinology, I have no sub-speciality training in endocrinology.

15

16

Q. No, as part of the sub-speciality as a pediatrician you do study the area of endocrinology, do you not, Doctor?

17

18

A. To a certain degree.

19

Q. Have you ever heard or studied

a condition known as "Transient Adrenal Insufficiency"?

20

21

A. I must say I am not familiar with that condition.

22

Q. Never heard of it?

23

24

A. Not that I can recall. I can tell you truthfully I have never seen a patient in

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FF3

whom I thought that was a diagnosis. I may have missed it, but I am not aware that I ever saw a patient with that problem.

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10

Q. Thank you. Now, Doctor,

Mr. Scott in his examination of you yesterday discussed certain BUN levels and potassium levels from St. Joseph's Hospital and from Chedoke McMaster Hospital.

11

A. Excuse me, I'm going to get a copy of the chart.

12

13

14

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Q. This unfortunately for you,

this is not contained in the chart, but you can get the chart, 106 is the exhibit number. I am afraid, Mr. Commissioner, I am probably in possession of these here, and these are the only copy of the blood level report from the Chedoke McMaster Hospital.

THE COMMISSIONER: Can we put it

forward as an assumption and I take it at some time we will prove it, is that all right?

Yes, Mr. Olah?

MR. OLAH: Yes, Mr. Commissioner, I'm

just wondering if it would perhaps be appropriate to mark that today and maybe have it distributed or copied at some future date, I think it might be of assistance to many of us to have some of this



FF4

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documentation.

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4

MR. SHINEHOFT: You see I have, Mr. Commissioner, three charts; I have the chart from the St. Joseph's Hospital where this baby initially attended. I have the chart from Chedoke McMaster Hospital, where the baby was transferred. Then of course I have the chart from the Hospital for Sick Children.

5

6

7

8

9

THE COMMISSIONER: Now, how big are these charts? Are these something I take it that we can have copies made from?

10

11

12

13

14

15

MR. SHINEHOFT: They are divided in the binder in which I have these documents, and I am certainly prepared to provide them to Mr. Elliot and to Miss Cronk for the purposes of reproduction.

16

17

18

19

20

THE COMMISSIONER: All right. Why don't we make the St. Joseph's chart then Exhibit 278; and the Chedoke McMaster chart Exhibit 279. Now, I take it you have no copies of those at the moment.

21

22

23

24

25

MR. SHINEHOFT: No, I am sorry, I don't.

26

27

28

MS. CRONK: I will see that they are made, sir, if Mr. Shinehoft will loan it to me.

---EXHIBIT NO. 278: Medical Chart re Kevin Pacsai, St. Joseph's Hosiptal.



FF5

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---EXHIBIT NO. 279: Medical Cart re Kevin Pacsai,
Chedoke McMaster Hospital.

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MR. SHINEHOFT: Q. I just want to

refer specifically to one page in the - this is the

Chedoke McMaster Hospital, Doctor, you will see on

the left hand side of the page there is the chemistry

report and they progress to the right side of the page.

9

10

A. Is it each column a different

11

date?

12

Q. It is a different time.

13

A. A different time.

14

Q. The date is at the bottom,
Doctor. You will see it is 8/3, 8/3 and then I think
this is the next day.

15

A. So these are all on March 8th
at different times.

16

Q. At different times.

17

A. Okay.

18

Q. Now perhaps if you could just
read the two levels ---

20

A. Where is the time denoted.

21

Q. It isn't unfortunately. Well,

22

it is right at the top, it is really undecipherable,

23

but if you could just review for us, Doctor, the

24

levels both as far as the potassium is concerned and

25



Kauffman, cr.ex.
(Shinehoft)

FF6

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3

as far as his BUN readings are concerned, do you see
where they are, Doctor?

4

A. Yes, I see where they are.

5

6

There are five potassium concentrations and serum
reported. The fifth one I don't see what the date is,
what the others are dated 8/3.

7

Q. So that will be after he left
St. Joseph's Hospital, is that not correct, Doctor?

9

THE COMMISSIONER: I am sorry, I thought

10 these were from St. Joseph's.

11

12

MR. SHINEHOFT: No, they are from
Chedoke McMaster.

13

14

Q. And St. Joseph's Hospital is
the one we discussed yesterday, the level of 7.4?

15

A. That is correct.

16

17

18

Q. Now these are, as I understand
it, and correct me if I am wrong, Doctor, subsequent
to that, this is after his transfer from St. Joseph's
Hospital to Chedoke McMaster.

19

20

21

A. These must have been done at
Chedoke McMaster Hospital because that is the name
on the laboratory sheet.

22

23

Q. If you could just review for
me the levels that they indicate both of the potassium
and of the BUN.

24

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FF7

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A. Okay. The first one is a

potassium, serum potassium 5.6. The second one is a serum potassium 4.6. The third one is a serum potassium 3.1. The fourth one is serum potassium of 4.5. The fifth one is serum potassium of 4.1.

Q. The 4.5, is that slightly hemolyzed at the bottom of that?

A. Yes, I didn't notice that, it is reported as slightly hemolyzed.

Q. So could you conjecture a picture of his potassium from the time that he initially arrived at McMaster Medical Centre to the time that he left, is there any picture that is given of going up, going down, remaining the same, what would you say about it?

A. Well, based on this information over this period of time that these were obtained, I would say his potassium level was staying within the normal range. It did fluctuate from a high of 5.6 to a low of 3.1.

Q. Yes, which would certainly ---

A. These are all, the 5.6 might be a little bit elevated, that was the first one when he arrived, but it is marginal, the others I think are quite satisfactory.

Q. What is your definition of a



Kauffman, cr.ex.
(Shinehoft)

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FF8 normal or a safe level of potassium?

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A. It depends on the laboratory norm. In general in a baby this age I would accept outside levels of 3 to 5½. Somebody might argue with me a little bit on either end but I think that is a fair range.

8

9

Q. I will tell you this, Doctor, other clinicians have said 3.5 to 5.5.

10

11

12

13

14

A. Well, I wouldn't argue with that, again what are your laboratory norms in that Hospital? I do studies for drug companies and they always make me select the norm for our laboratory because they will not interpret the numbers until they have all the norms.

15

16

17

18

Q. So he has a level of slightly over 4, the last level taken at McMaster Medical Centre, and then he arrives at the Hospital for Sick Children and I understand he has a level of 3.9 upon his arrival at the Hospital.

19

20

21

A. That is my recollection.

Q. And what do you have to say

about that level, Doctor?

22

A. I think that is normal also.

23

Q. Now what about his BUN - I

24 was going to ask you about his BUN levels?

25



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FF9 A. The first one that is reported on the sheet at Chedoke McMaster Hospital is reported as 34. The next one is 38. The next one is 33. The next one is 27. The next one is 1.9. The last one that is on this sheet is at 19.

Q. What do you have to say about that in comparison to a normal BUN reading?

A. These are all elevated except the last one and it is high range of normal.

Q. And what about his BUN level on his admission to the Hospital for Sick Children?

A. I don't remember what it was offhand.

Q. I don't either.

A. We will see what it is.

Q. It is less than 5 on his arrival at the Hospital.

A. Okay.

Q. Do you have an opinion as to what ---

A. I think 19, 19 is borderline high for a baby this age, less than 5 is normal.

Q. So would it be fair to say his potassium and his BUN levels upon his arrival at the Hospital were normal, or within normal limits?



Kauffman, cr.ex.
(Shinehoft)

FF10

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2 A. Yes, I think so, at the Sick
3 Children's Hospital.

4 Q. At the Sick Children's Hospital?

5 A. Yes.

6 Q. Doctor, you have in your rating
7 for Kevin Pacsai have rated him from a 1 to 5 and
8 you rated him as a 4, is that correct?

9 A. Without referring to my CDC
10 sheets I think that is correct. I have my summary in
11 front of me here.

12 Q. Would you mind referring to
13 your CDC sheets.

14 MS. CRONK: Exhibit 273, Doctor.

15 THE WITNESS: This is a summary of
16 my CDC rating, and yes, Kevin Pacsai was included in
17 the 4 patients given a rating of 4.

18 MR. SHINEHOFT: Q. I am curious to
19 know, Doctor, of the five criteria that you have
20 selected in order to be included in No. 5, it seems
21 to me that the one criteria that Kevin Pacsia did
22 not fit in was that he was prescribed digoxin,
23 correct, prior to his admission to the Hospital in
24 Toronto.

25 A. Let me check and I will answer
26 you. I am sorry.



Kauffman, cr.ex.
(Shinehoft)

FF11

1
2
3 Q. Okay. This is the letter
4 dated December 14th from Dr. Smith, do you recall
5 that where you set up your criteria?

6 A. Yes.
7
8 Q. Do you have that letter, Doctor?
9 A. Yes.
10 Q. And you indicate for rating 5
11 that patients receiving this rating meet at least
12 four of the following criteria, and the fifth criteria
13 is no digoxin prescribed at time of death?
14 A. That is right.
15 Q. I think we discussed it.
16 THE COMMISSIONER: Excuse me,
17 Mr. Shinehoft, this is what exhibit?
18 MR. SHINEHOFT: It is Exhibit No. 272,
19 Mr. Commissioner.
20 THE COMMISSIONER: Thank you. What
21 tab is it, what number?
22 MR. SHINEHOFT: It is Tab 1.
23 THE WITNESS: You are speaking of
24 page 3?
25 MR. SHINEHOFT: Q. Page 3, Doctor,
criteria used to rate the probability of death
resulting from digoxin intoxication.
A. Yes.



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FF12

Q. For a rating 5 you have given 5 criteria of which a patient has to fall within 4 of the 5?

A. That is right.

Q. Now it would appear to me then that you are of the opinion that Baby Pacsai did not come within 4 of 5?

A. That is correct.

Q. Which one, which of these did he not come within, in your opinion?

A. He didn't, I don't think he met criterion, we are talking about rating 5 now?

Q. Yes.

A. I am going from memory of his circumstances now, and I may need to refer to the chart.

Q. You have the chart in front of you, Doctor.



1

2 THE COMMISSIONER: You didn't have -

3 I think I can answer.

4 THE WITNESS: Yes, here we go.

5 MR. SHINEHOFT: Q. Yes, it is No. 5.

6 I am aware I believe that he doesn't come within
7 the parameters of guideline No. 5; is that correct,
8 Doctor?

9 A. That is right.

10 Q. But which other one did he not
11 come ----

12 A. The other one he did not
13 achieve in my judgment was ante mortem concentrations
14 well above therapeutic range.

15 Q. Well, Doctor, you are aware
16 of the ante mortem levels that he had?

17 A. Of 10.

18 Q. Of greater than 10?

19 A. Well, it was somewhere there.

20 Those ante mortem levels.

21 Q. I am talking ante mortem.

22 A. Yes, but you see the key word
23 here is unequivocally toxic range, and my problem
24 was I didn't know how much above 10, and we know
25 that I have seen it in my personal experience there
are babies who have levels within the 10 range that



1

2 don't show toxicity so I couldn't say he was
3 unequivocally in the toxic range.

4 Q. No, but if you could answer
5 this question, Doctor, what is the therapeutic range
6 of digoxin?

7 A. Well, for babies it is poorly
8 described, but the usually clinically used range is
9 somewhere in the neighbourhood of .8 to 3 nanograms
per millilitre.

10 Now some people will say 1 to 3,
11 some, .8 to 2.5, but I will take it .8 to 3.

12 Q. So his level, his ante mortem
13 level is at least three times the normal therapeutic
14 level, possibly more? That is the upper range of
15 the therapeutic level? Is that correct, Doctor?

16 A. Well, you are describing it
17 in terms of therapeutic range. I am describing it
in terms of unequivocally toxic.

18 Q. I just want to get ---

19 A. His level was apparently at
20 least 3 times the range that we usually accept as
21 a satisfactory serum concentration during therapy.

22 Q. Isn't that ---

23 A. But it is not 3 times a
24 concentration that we not uncommonly have seen in

25



Kauffman, cr.ex.
(Shinehoft)

1

2 children who are not showing any toxicity.

3

4 he not? He shows the high levels in his blood ---

5

6 A. Well, he exhibited symptoms
7 that were quite compatible with digoxin toxicity in
8 my opinion.

9

10 Q. So am I correct in saying,
11 Doctor, that if the criterion No. 2 were changed
12 slightly to read ante mortem serum digoxin con-
13 centrations in the toxic range, and deleted the
14 word "unequivocally", then would you be of the
15 opinion that he would rate a 5?

16

17 A. No, because he doesn't meet -
18 well, four of the five, but I very deliberately and
19 advisedly made it so that it had to be clearly outside
20 what I could accept as being there but not producing
21 toxicity.

22

23 Q. I see. But if he were in
24 the bata phase of distribution.

25

26 A. If I changed any of my criteria
27 I could re-juggle the patients in the categories
28 obviously.

29

30 Q. I am just talking about one
31 word.

32

33 A. Well one word can be terribly

34

35



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2

important.

3

4

Q. I agree, but you are saying
that 10, even though it is high, and even though it
is outside the normal therapeutic level isn't in your
opinion unequivocally toxic?

5

6

7

A. No. In and of itself it is
not unequivocally toxic.

8

9

Q. And that is why he was given
a rating of 4 as opposed to 5?

4

10

11

12

THE COMMISSIONER: Doctor, I just
wonder - I am sorry, do you want to answer that
question? Is he answering that question yes?

13

14

THE WITNESS: I think that is part
of the reason, yes.

15

THE COMMISSIONER: I am just wondering
if he satisfied Item 4 under Rating 5?

16

17

THE WITNESS: Well, no, because he
didn't have fresh autopsy tissue.

18

19

THE COMMISSIONER: And that was one of
the problems too, is it?

20

21

22

23

THE WITNESS: I had several problems
with putting him in No. 5. I didn't have fresh
autopsy tissue data on him, and his ante mortem serum
was equivocal, and there was no way I could justify -
well, I thought he fit the grading 4 criteria.

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MR. SHINEHOFT: Q. Doctor, if I

could ask you about the relationships now of potassium and digoxin, the issue of hyperkalemia and elevated digoxin. I believe your evidence has been that one often follows the other but is not necessarily coincidental to the other. Is that a fair restatement?

A. They are not uniformly

associated.

Q. And that would be - and what

you are meaning I assume is that an elevated digoxin level may cause an elevated potassium level?



GG2-1

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2

A. Yes, but not - it hasn't in
all reported cases.

4

Q. But it can happen?

5

A. It can, yes.

6

Q. Now what about the opposite of
that, Doctor, and I believe you have given some
evidence about that.

8

You see there are some paediatricians
that believe the opposite, that people with elevated
potassium level can cause an elevated digoxin level.
Would you agree with that?

11

A. No, I don't. If I understand
the question I don't agree with that.

13

I know of no evidence, no data that
substantiates that elevation, independent elevation
of potassium will cause a detectable or measureable
elevation of serum digoxin concentration.

17

Q. So you have never seen anything
in the reported literature --

19

A. I am not aware of anything
that would substantiate that statement. If it is
I don't know about it.

21

Q. Well, we have had some people
who have maintained that theory, but you are saying
you know of no reported literature that substantiates
that theory?

25



Kauffman, cr.ex.
(Shinehhoft)

GG2.2

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2 A. No, I am not aware of it.

3

Q. All right. Are you prepared
4 to give us an estimate as to the percentage of cases
5 where an elevated digoxin level would produce an
6 elevated potassium level or you have no --

7

A. I have no basis on which to
give you a percentage.

8

Q. Okay.

9

A. In response to your question
10 about the potassium and digoxin, potassium causing
11 an elevation of digoxin, I don't know if this is
12 relevant or not, but it is true that potassium, an
13 elevated potassium will tend to reduce the pharmacologic
14 effects of digoxin where a low, an abnormally low
15 potassium will tend to increase the pharmacologic
effect.

16

Q. It is one of the known antidotes
17 for high levels of digoxin?

18

A. Yes, but I don't equate that
19 with increasing the level of digoxin in the serum.

20

Q. Well, Doctor, Mr. Scott
21 discussed with you certain assumptions that you have
22 made in order to come to the findings that you have
23 made, and I believe that you agreed with him
yesterday if you changed some of the assumptions

24

25



GG2.3

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2 perhaps some of the results might be changed?

3

A. Yes.

4

Q. Now if I could ask you
5 specifically about Kevin Pacsai, and to give you what
we do know, we know what his ante mortem level of
6 digoxin was; we know what his post mortem --

7

A.

We don't know definitively

8

what it was.

9

Q.

We know approximately what

10

it was.

11

THE COMMISSIONER: We have a minimum.

12

THE WITNESS:

We have a minimum and
a maximum. We know it was some place between 10 and
13 25 or 26, and that is a two and a half fold variation,
14 and at least I don't have any idea where within that
15 range it really was.

16

MR. SHINEHOFT:

Q. Fair comment, but
we know it was at least 10?

17

A.

Right. I will accept that.

18

Q.

And we know that after his

19

death it was approximately 25.5?

20

A.

In post mortem samples.

21

Q.

We know what his potassium

22

levels were?

23

A.

Yes.

24

25



GG2.4

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2 Q. And we know what his BUN levels
3 were?
4 A. Yes.
5 Q. Correct?
6 A. Yes.
7 Q. And we know a couple of other
8 blood gases, creatinine and sodium and things like
9 that?
10 A. Yes.
11 Q. Now if you were to change any
12 of your assumptions with regard to the child Kevin
13 Pacsai keeping in mind what we do know, would your
14 opinion of his cause of death change or the category
15 that you have placed him change?
16 A. Well, you would have to ask
17 me about specific assumptions and how I was going to
18 change them I think.
19 Q. I see.
20 A. Before I could respond to that
21 meaningfully.
22 Q. I see.
23 A. You see, I made certain
24 calculations to calculate a minimum dose that might
25 be possible.
To do this, my pharmacokinetic



GG2.5

1

2 assumptions did not impact on my decision as to
3 whether or not the probability of the relationship
4 of digoxin to his death - they were simply used to
5 then say if indeed digoxin was related to his death,
6 what is a minimum dose that might have produced this
7 situation based on these assumptions.

8

9 Q. But there are certain knowns
10 that form part of your formula as well, and I just
11 reviewed them with you, the ante mortem levels, post
12 mortem levels and things like that.

13

A. Right.

14

15 Q. And I am saying could you
16 formulate an opinion, just on that information alone
17 without making these other assumptions?

18

A. Which opinion?

19

20 Q. As to the cause of death or
21 as to what category it would place him in?

22

23 A. Well, if you are talking about
24 the assumptions I made in terms of volume of
25 distribution - are those the assumptions you are
26 talking about?

27

Q. Yes.

28

29 A. Because I am not sure that I
30 understand your question.

31

32 Q. I perhaps have worded it badly.

33

34

35



GG2.6

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A. My assumptions were that 70% of the dose was absorbed, that he had an elimination half life of 30 hours; that distribution equilibrium had been completed so the volume of distribution was 10 metres per kilo; but there was an interval between the dose and death of 6 hours, and that the serum concentration at the time of death was in the mid range of hour extremes, 15 nanograms per ml.

Q. You used 15 I think.

A. And an elimination rate constant of .0231. And then based on those I calculated a minimum dose.

-



GG-3-1 1

EMT/cr 2

Q. Are those assumptions ---

3

A. Those assumptions didn't

4

have any direct relevance to my probability rating.

5

They were simply used to try to come up with some ball park estimates of a feasible dose.

6

Q. So it had nothing to do with
7 where you rated this baby?

8

A. No, I didn't need to go
9 through the dosing exercise to write this baby.

10

Q. You had enough information
11 from his chart?

12

A. I didn't have enough
13 information on any of these babies, but I worked with
14 what I had.

15

Q. Thank you, Doctor.

16

A. But I based my rating on
17 whatever information I had.

18

Q. Now, Doctor, you had given
19 some opinions and the Murphy child was discussed
20 with you yesterday and I believe you gave evidence
21 at the Inquest of Gary Murphy?

22

A. That is correct.

23

Q. I would like to discuss Gary
24 Murphy and Kevin Pacsai because there seems to be
25 some similarities or some people think there are



1

2 some similarities between the two.

3 I would like to ask you about, in your
4 opinion, if there were any anatomical differences
5 between the two?

6 A. Well, there were extreme
7 anatomical differences between the two.

8 Q. Is it your opinion or do you
9 have an opinion as to whether these anatomical
10 differences make it impossible really to make a
11 comparison between the two? In other words, to use
12 your phraseology, are you comparing apples and oranges
13 when you compare Murphy and Pacsai?

14 A. Well ---

15 THE COMMISSIONER: Not his exclusive
16 phraseology. It seems to me I have heard that
17 expression before.

18 MR. TOBIAS: I take some credit for
19 that.

20 THE COMMISSIONER: All right, Mr.
21 Tobias invented it then.

22 MR. SHINEHOFT: Q. Can we compare the
23 two I guess is what I am saying.

24 A. I cannot put those two patients
25 in the same category at all.

26 The only similarities that I really see



Kauffman, cr.ex.
(Shinehoft)

3-3

1
2 is that their post mortem serum concentrations were
3 almost identical, and there was one other similarity
4 that I can't remember - I think that neither of them -
5 no I can't remember what it was now. There was some
6 other minor similarity and I can't remember what it
was.

7 Q. Did they both have renal
8 failure?

9 A. But I may have commented on
10 it in my testimony.

11 Q. The BUN levels on both of them
12 were ---

13 A. Well, it wasn't very impressive
14 on either one of them.

15 Q. Neither had renal failure?

16 A. No, I couldn't see any evidence
17 of renal failure in either one of them. But there
18 were other major differences between them.

19 Gary Murphy was six or seven months
20 old; Kevin Pacsai was a few weeks old.

21 Gary Murphy had severe cyanotic heart
22 disease with a very complex anatomical abnormality.
23 Kevin Pacsai had no anatomical abnormality, and when
24 he didn't have his dysrhythmia he seemed to be
25 oxygenating and having normal cardiac output as near



1
3-4 2 as I could tell from reading his record.

3 Gary Murphy had a prolonged progressive
4 downhill course with an irreparable heart defect,
5 and the decision had been made not to take aggressive
6 intervention but to keep him comfortable and let
7 nature take its course.

8 Kevin Pacsai was an apparently healthy
9 looking baby but then got sick shortly for a period
10 of time prior to his admission, and then almost died
11 from a dysrhythmia that is described at least one
place as paroxysmal atrial tachycardia.

12 Q. Yes.

13 A. And went into shock.. But then
14 once that reversed, things reverted to normal, by
15 the time he arrived to Sick Children's Hospital he
16 seemed to look, from what I can tell, pretty good for
17 the next few hours until he developed an irregular
18 heartbeat again. So I see many more differences
between these two babies than I see similarities.

19 Q. So it is really impossible
20 to make that analysis or comparison would you agree?

21 A. I don't see them as comparable
22 at all other than their post mortem digoxin
concentrations.

23 Q. Finally, Doctor, there is some

24

25



1

2 evidence in the chart of Kevin Pacsai that he after
5 his arrival to the I.C.U. went back into normal
3 sinus rhythm for a short period of time.
4

5 A. You mean after his initial ---

6 Q. He was seen by Dr. Costigan
7 on the ward at I believe 5:30 in the morning and he
8 was transferred to I.C.U. around 6 o'clock, and
9 apparently there is in the chart something to the
10 effect that he went back into normal sinus rhythm
11 for a period of time and no one really knows how short
12 or how long that period of time is.

13 A. I would have to refer to the
14 chart but I do recall something where there was a
15 short period of a nodal or sinus rhythm described
16 around that time. I would have to refer to his
17 chart to answer you.

18

19

20

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25



Kauffman
cr.ex. (Shinehoft)

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2dec83 2
HH
BMcra 3

I would have to refer to the chart
to answer you.

4 Q. Well, perhaps you could refer
5 to his chart, page 66. Have you got his chart there,
6 doctor?

7 A. Yes, I am looking at page 66
8 of the chart.

9 Q. A 23-day old baby.

10 A. Yes, sure. That is the ICU,
11 one hour later bradycardia, 2 to 1 block noted,
12 prolonged PR. On leaving ward developed bradycardia
13 down to 40, cyanosis, brief apnea, further episodes
14 of bradycardia and 3 to 1 block.

15 Q. Maybe it is not when he was
16 immediately transferred. There is some indication
17 in one place in the chart, and I just can't find it,
18 I will continue looking for it, Doctor, and he went
19 back for a period of time to normal sinus rhythm.

20 Do you recall reading that in his
21 chart?

22 A. I vaguely recall reading that
23 someplace but I can't find it now in his resuscitation
24 notes.

25 Q. Would that surprise you if the
child had received --



HH

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4

A. I'm sorry, there is a note on
March 12 on page 70 that says, "Child had sinus
rhythm last night, problem began this a.m.".

5

Q. Maybe that's it.

6

7

8

9

10

A. "X-ray reported normal, heart
size plus no (something) edema,
arryhthmias noted, ventricular
fibrillation, could not be revived,
no obvious underlying cause, agree
with treatment."

11

12

That must have been a note by one
of the staff physicians.

13

14

15

16

Q. Now, if the child had an
overdose of digoxin, is it possible that the child
could revert back to normal sinus rhythm for a
period of time before showing signs of digitalis
toxicity?

17

18

THE COMMISSIONER: After showing
signs and before dying.

19

20

MR. SHINEHOFT: Q. After showing
signs and before dying.

21

22

A. During the course of toxic
symptomatology.

23

24

25

MR. OLAH: I think the reference that
he is looking for is at the bottom of page 69.



Kauffman
cr.ex. (Shinehoft)

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HH3

2 MR. SHINEHOFT: Thank you.

3
4 MR. OLAH: I think it is the last
five lines at the bottom of the page.

5
6 THE WITNESS: Okay, on page 69 at the
bottom.

7
8 MR. OLAH: The second-last line,
Doctor.

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THE WITNESS: "During the evening
the patient became bradycardic with
2 to 1 and 3 to 1 A/V block - to the
ICU, atropine was given, rate
regular, sinus rhythm."

And then they've got the high potassium and we are
treating the potassium and then he went back into
ventricular fibrillation apparently shortly thereafter.

Q. Yes, returned to sinus
rhythm.

A. So, he was doing a lot of
different things during this time. He was having
changing heart rate, he was having variable conduction
block, he was reverting to a different kind of
rhythm and eventually went into ventricular fibrilla-
tion from which he could not be resuscitated.

Q. Right. Does the fact that
this child went back into sinus rhythm, is that



1
HH4 2 unusual in a situation like this?

3
4 A. I can answer it to the
5 extent that it is consistent with some of the
6 reports in the literature of what happens with the
7 heart during digoxin toxicity and non-intoxication
8 and I suspect that what is going on is that the
9 digoxin has the electrical characteristics of the
10 heart so deranged that you have multiple sites in
11 the heart initiating depolarization so that you have
12 changing blocks, changing rates and an extremely
13 irritable heart, and it has been described in
14 published cases occasionally that a part of this
15 whole picture can include a brief time of what
16 appears to be a sinus rhythm followed then by some
17 more severe arrhythmia.

18
19 So, it doesn't particularly surprise
20 me, and it certainly doesn't suggest to me in the
21 face of everything else that it is not digoxin
22 intoxication.

23 Q. You wouldn't happen to have
24 the reference to the literature?

25 A. I would have to go through
26 my stack of the literature. This kind of thing is
27 described in some of the individual case reports. It
28 would take me a while to look it up but I could do
29 that sometime.



BmB.jc
JJ2.1

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Q. But that didn't alter your
opinion, it didn't eschew it?

4

5

6

A. No, because of being aware of
this kind of pattern in describing the cases of
digoxin intoxication, that didn't particularly bother
me.

7

8

MR. SHINEHOFT: Thank you very much,
Doctor, those are my questions.

9

10 THE COMMISSIONER: Now, Mr. Shanahan,
what is your position going to be on the 19th?

11

12

MR. SHANAHAN: As I say, on the
morning of the 19th I am in tight quarters.

13

14

THE COMMISSIONER: Well, how long
would your examination be?

MR. SHANAHAN: Well ...

15

THE COMMISSIONER: Quite a while?

16

17

18

MR. SHANAHAN: No, no. I think I
suppose about a half an hour. I would like to say
15 minutes but I don't think I will.

19

20

THE COMMISSIONER: Well, I don't
think we can trust the Toronto rush hour.

21

22

23

24

25

MS. CRONK: Mr. Commissioner, could I
make a suggestion, sir. I will speak to Mr. Shanahan
and see what we can work out for the 19th but we do
have about 15 minutes and if that is all Miss Symes



JJ2.2

1

2 is going to be may I suggest she finish it today.

3

4 THE COMMISSIONER: Well, I don't
5 think Miss Symes can finish in 15 minutes, that's the
6 problem. I really want the doctor to get away at a
7 quarter to five.

8

9 Yes, Mr. Tobias, you're in trouble?

10

11 MR. TOBIAS: Yes. I may not have a
12 problem at all. I didn't anticipate that Miss Symes
13 would be re-examining on the 19th. Certainly if she
14 anticipates being anything more than a half an hour
15 or forty minutes --

16

17 THE COMMISSIONER: I am going to
18 take times right now and hold people to them and we
19 will try to sort people out. The first thing,
20 Dr. Kauffman, I think, thank you very much, we would
21 like you to go now. I'm not being rude.

22

23 THE WITNESS: Okay, I will pack up
24 and get ready to leave.

25

26 THE COMMISSIONER: I don't know what
27 the Detroit rush hour is like but Toronto rush hour
28 is god-awful and I think you should be on your way.

29

30 THE WITNESS: Thank you.

31

32 MR. ORTVED: Mr. Commissioner, I know
33 how much you are going to welcome this but I have a
34 matter of housekeeping of about two minutes that I

35

36



JJ2.3

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2 completely forgot about this morning.

3

THE COMMISSIONER: Yes.

4

MR. ORTVED: May I?

5

THE COMMISSIONER: With Dr. Kauffman?

6

MR. ORTVED: Yes.

7

THE COMMISSIONER: Yes, all right.

Some housekeeping that is going to be two minutes.

8

THE WITNESS: All right.

9

CROSS EXAMINATION BY MR. ORTVED:

10

Q. Dr. Kauffman, I'm sorry, but

11

this morning I just wanted to ask you very briefly
about your reference on Exhibit 273 and 274 regarding
Brian Gage. You will notice there under your heading
Cause of Digoxin Intoxication opposite Brian Gage on
both of those exhibits there is reproduced there the
reference in the rating sheets to pre-existing
intoxication due to prescribed doses, correct?

17

A. Yes.

18

Q. What I on behalf of the doctor
wanted to ensure here, because I understand from the
balance of your testimony that you are not suggesting
that it was the prescribed doses leading to the value
of 3.5 that killed this baby?

22

A. No. What I was referring to
in the wording is poor and that reflects my informal

23

25



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Kauffman, cr.ex.
(Ortved)

6523

JJ2.4

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2 handwritten notes at the time. What I was referring
3 to was a baby who had an increase in his concentration
4 consistent with an increase in the dose prior to his
5 getting into trouble.

6

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BB/cr

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2 O. All right, that is all I
3 wanted to cover off. Thank you, Mr. Commissioner.

4 THE COMMISSIONER: All right, thank
5 you. Thank you then, Doctor.

6 ---Witness withdraws.

7 THE COMMISSIONER: Now, Miss Symes,
8 15 minutes and you will just have to sort yourself
9 out, that is all you will have is 15 minutes on the
10 19th.

11 Now, Mr. Olah, how long do you expect
12 to be?

13 MR. OLAH: I would expect to be about
14 a half an hour, Mr. Commissioner.

15 THE COMMISSIONER: Miss Jackman?

16 MS. JACKMAN: An hour.

17 THE COMMISSIONER: Mr. Labow?

18 MR. LABOW: A half an hour, Mr.
19 Commissioner.

20 THE COMMISSIONER: All right. Now,
21 Mr. Tobias?

22 MR. TOBIAS: A half an hour, Mr.
23 Commissioner.

24 THE COMMISSIONER: Well now we have
25 two and three-quarter hours on the 19th. What is
your - you don't need to answer this question but does



1

2 your engagement take you longer than that?

3

MR. SHANAHAN: My engagement!

4

Sir, my commitment is at 10 o'clock in the morning.

5

THE COMMISSIONER: What sort of
a commitment is it?

6

MR. SHANAHAN: If we were to start
early on that morning on the 19th and I was to be
permitted to go first.

9

THE COMMISSIONER: Well, what sort of
an engagement do you have?

10

MR. TOBIAS: I would advise you not
to answer that, Mr. Shanahan, unless you have a very
good answer.

11

MR. SHANAHAN: This is getting to be
very romantic. It is fairly and simply, sir, to be
in two different provincial courts at the same time,
the old criminal lawyers stuff.

12

THE COMMISSIONER: Well, are you
counting this as one of the provincial courts?

13

MR. SHANAHAN: No. It is two
provincial courts, sir, in the old conundrum that
the criminal lawyers face. If it were to start
early, sir, then I could ---

14

THE COMMISSIONER: How long are you
going to be.

15



1

2 MR. SHANAHAN: I would think I would
3 be 15 minutes to a half hour, that range.

4 THE COMMISSIONER: Well, I am going
5 to give you 22½ minutes then.

6 Well, what I want to do is, I want
7 to start in and let Mr. Hunt and Miss Cronk have the
8 afternoon but it is conceivable that we could - I
9 take it these provincial courts don't function in
the afternoon, or do they?

10 MS. SYMES: They don't function at
11 any time.

12 MR. SHANAHAN: There are people here
13 from the Crown Attorney's office, so, I won't give
any secrets.

14 Now, you see, at the other end, sir,
15 around 11 or 11:30 I would probably be reached here
16 and that is really my worst time out there, I
17 apologize.

18 THE COMMISSIONER: Well, no, why don't
19 we put you on at ---

20 MR. SHANAHAN: If I got started early
here then I would be out of here.

21 THE COMMISSIONER: Well, could you go
22 on at 2:15?

23 MR. SHANAHAN: That would be perfect.

24

25



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2

THE COMMISSIONER: 2:15 then, or
2:30.

4

Have you any thoughts on how long you
5 will be?

6

MR. HUNT: I would think about an
hour to an hour and a half.

7

8

9

10

THE COMMISSIONER: Well, I think what
we will do is, we will give Mr. Shanahan 20 minutes
in the afternoon. You can be here by 2:15 without
any trouble?

11

12

13

MR. SHANAHAN: I might say too, sir,
that I am going to speak to Miss Cronk because there
may be a lot of areas here that - I just won't say
any more but she may be able to carry the load.

14

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THE COMMISSIONER: Well, all right.
We will worry about that. But in any event, I am
going to ask all of you to complete and Mr. Tobias
if you are the last on the list you will have your
full half hour anyway so that we may have a chance
at 12:30 to complete. I am going to have to hold
people to the times because we have no control over
this witness at all. If he doesn't want to come back
there is just no conceivable way that I can force
him to come back, and we are grateful that he has
come back. Now, that being the case, we are not



1

5 2 sitting Monday morning because of the Council of
3 Judges. We will sit at 2:30 on Monday. So, we will
4 rise until 2:30 and then Dr. Hastreiter will be here
5 at 2:30 on Monday.

6

7 ---Whereupon the hearing adjourned at 4:40 until
8 Monday, the 5th day of December, 1983 at 2:30 p.m.

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